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A CLUSTER ANALYSIS BASED ON THE HEALTH BELIEF MODEL OF ALACARE PATIENTS AT HIGH RISK FOR OSTEOPOROSIS

by

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A DISSERTATION

Submitted to the graduate faculty of the University of Alabama at Birmingham, in partial fulfillment of the requirement for the degree of Doctor of Philosophy

BIRMINGHAM, ALABAMA

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A CLUSTER ANALYSIS BASED ON THE HEALTH BELIEF MODEL OF ALACARE PATIENTS AT HIGH RISK FOR OSTEOPOROSIS

ELIZABETH M. KITCHIN

HEALTH EDUCATION AND HEALTH PROMOTION

ABSTRACT

The prevalence of osteoporosis and subsequent fragility fractures will continue to rise as the American population ages. The high personal and medical costs of fragility fractures have been well documented. Taking calcium and vitamin D supplements are important strategies for lowering the risk of sustaining a fragility fracture and for improving the efficacy of prescription osteoporosis medications. The purpose of this study was to determine if patients in a home health setting in Alabama (Alacare) who are defined as high risk for a fragility fracture could be segmented via cluster analysis based on the constructs of the Osteoporosis Health Belief Subscales. We analyzed baseline data gathered as part of the parent study, Improving Osteoporosis Care in High-Risk Home *Health Patients through a High-Intensity Intervention*, using two-step cluster analysis. We then analyzed the groups formed in the cluster analysis using either ANOVA or independent *t*-tests to evaluate if group membership was related to intake of calcium supplements, vitamin D supplements, multivitamins, and dietary calcium intake. Gender and a self-reported doctor diagnosis of osteoporosis emerged as the most important influences on group membership in four different cluster analyses. The constructs of the health belief model were weak influences of cluster membership when gender and selfreported doctor diagnosis of osteoporosis were included as clustering variables. When gender and doctor diagnosis were not included as clustering variables, two measures of perceived benefit of supplements influenced group membership. Statistically significant

differences for number of reported days taking calcium and vitamin D supplements were found for groups in each of the four cluster analyses with women and patients with a selfreported doctor diagnosis of osteoporosis reporting a greater number of days taking supplements. In the cluster analysis that excluded both gender and doctor diagnosis of osteoporosis, the groups had statistically significant differences for reported number of days taking a multivitamin as well. There were no differences among the groups in any of the analyses for dietary calcium intake.

Keywords: osteoporosis, cluster analyses, home health, fracture risk

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CHAPTER 1

INTRODUCTION

Osteoporosis is a skeletal disease characterized by low bone mineral density and compromised bone architecture, increasing the risk of fragility fractures, particularly in the older population (National Institutes of Health (NIH) Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy, 2010). Fragility fractures are a major cause of disability, institutionalization, death and a lower quality of life (Fraser 2004; Ribeiro, Blakely, & Laryea, 2000). Osteoporosis contributed to 2 million fractures in 2005 at an estimated cost of \$19 billion (National Osteoporosis Foundation, 2010). The National Osteoporosis Foundation (NOF) estimates that the number of osteoporotic fractures will reach 3 million yearly by 2025 with costs reaching an estimated \$25.3 billion (2010).

Factors that increase the risk of osteoporosis and fragility fractures are both genetic and behavioral and are often categorized as "modifiable" and "non-modifiable" (NOF, 2010). Non-modifiable factors include female gender, being post-menopausal, increased age, use of certain medications such as corticosteroids, and family history of fracture. Modifiable risk factors include lack of bone bearing exercise, low calcium and vitamin D intake, smoking, and low body weight. Medications that improve bone density and bone microarchitecture, adequate calcium and vitamin D, and bone bearing exercise are the mainstays of osteoporosis treatment and fracture prevention (NIH, 2010; Wolf, Zmuda, Stone, & Cauley, 2000). Unfortunately, osteoporosis is often not diagnosed until after a fracture occurs, if at all. Challenges to increased diagnosis and treatment of osteoporosis include the failure of both physicians and patients themselves to recognize who is at risk. Researchers have found that physicians often fail to counsel at-risk patients about their risk of osteoporosis (Gallagher, Geling, & Comite, 2002). Many at-risk patients are unaware of their risk for osteopoporosis, fragility fractures and the existence of effective treatments that can lower fracture risk (Backett-Milburn, Parry, & Mauthner, 2000; Giangregorio et al., 2008; Meadows, Mrkonjic, Lagendyk, & Petersen, 2004). Other researchers have found that many at-risk people recognize the word "osteoporosis" but view the disease as relevant to others but not to themselves (Backett-Milburn et al., 2000; Burgener, et al., 2005).

Some research suggests that educating patients may be more effective than educating doctors in increasing the proper diagnosing of osteoporosis (Pazirandeh, 2002). However, a diagnosis of osteoporois may not be enough to motivate patients to take proper fracture preventive actions. Many patients who have sustained a fragility fracture do not perceive a relationship between the diagnosis of osteoporisis and their fracture or future fracture risk (Giangregorio et al., 2008; Meadows et al., 2004). Due to the increase in aging population's risk of osteoporosis and fragility fracture and the lack of timely diagnosis and treatment, researchers have begun and continue to seek effective ways of raising awareness and increasing osteoprotective behaviors in the high-risk population.

Theory based education and interventions may improve bone health behaviors including seeking diagnosis and treatment. The Health Belief Model (HBM; Janz, Champion, & Strecher, 2002) has been used as the theorectical framework to explain bone health behaviors and as the basis for OP education interventions. The HBM is a value expectancy theory in which the desire to avoid or treat illness (value) and the belief

that taking specific actions will be effective in doing so (expectancy) are influenced by the perceived threat of the illness. The likelihood of taking an action results from adequate perceived threat (a combination of perceived severity of and suceptibility to an illness) and the belief that the behavioral action is effective at treating or preventing the disease. The original model was developed to explain the failure of adults to take advantage of free tuberculosis screening programs in the 1950's. Since that time is has been used in a variety of preventive and treatment settings to both explain behaviors and as the basis for behavior change interventions.

Osteoporosis researchers have used the HBM in cross-sectional and intervention studies. Several researchers explored the predictive and intervention capabilities of the model in young and mid-age women at risk for developing osteoporosis and have examined behaviors such as weight-bearing exercise and calcium and vitamin D intake. Wallace (2002) found that the expanded health belief model (which includes selfefficacy) was useful in identifying associations between beliefs and exercise and calcium behaviors in college women. Hazavehei, Taghdisi, and Saidi (2007) used the health belief as the basis for an educatioal intervention aimed at middle school girls in Iran and found that the HBM was a feasible and affective model to promote increasing calcium intake, physical activity, and time spent in the sun.

Other researchers have explored the model's use in older adults. In an exploratory qualitative study, Jachna and Forbes-Thompson (2005) used the HBM to explore the perceived threat of OP in a small number of women (n = 5) in an assisted living facility who had experienced a fragility fracture. They found that most did not view osteoporosis as threatening (combined perceived severity and perceived susceptibility) as other health concerns despite having sustained fragility fractures. Using

a mailed survey of over 1,800 men and women age 60 years and older, researchers found that the majority of respondents believed osteoporosis to be severe but did not believe that they were personally in susceptibility (Nayak, S., Roberts, M.S., Chang, C.H., and Greenspan, S.L., 2010).

Researchers have also used the model to find associations between beliefs and behaviors in the older population. In a cluster analysis that segmented women into three subgroups with similar osteoporosis health belief profiles, Cline and Worley (2006) found that women fell into three distinct groups: those who believed they were susceptible to osteoporosis and perceived many benefits and few barriers to supplement use; women who believed they were susceptible to osteoporosis, that its consequences were serious and perceived significant barriers and few benefits to supplement use; and, women who did not perceive themselves to be susceptible to osteoporosis and had few opinions of supplement use. These groupings were predictive of some osteoporosis preventive behaviors.

Other researchers have used the HBM to design OP education interventions. In a study designed to evaluate three HBM-based osteoporosis prevention programs of varying intensity, researchers found that all of the programs were equally effective at increasing knowledge but none changed the participants' health beliefs nor increased OP prevention behaviors (Sedlak, Doheny, & Jones, 2000). Solomon et al. (2006) found that mailed intervention materials based on several OPHBM constructs did not increase the number of OP preventive behaviors in older adults.

While many studies have used the HBM as their theoretical basis, self-efficacy is rarely incorporated in the model despite its recognized importance. Rosenstock, Strecher, and Becker (1988) posited that the omission of self-efficacy from the HBM may mean

that the model has failed to account for as much variance in behavior as it might have had self-efficacy been incorporated into the model. Self-efficacy has been studied as an individual variable in older adults and with a variety of behaviors. Early studies show that self-efficacy is likely to play a role in the exercise behavior of older adults (Gill, Kelley, Williams, & Martin, 1994; Sallis, Hovell, & Hofstetter, 1992; Sharpe & Connell, 1992). Recent studies also support self-efficacy as a predictor and mediator of behaviors and attitudes in areas such as fear of falling, taking calcium supplements, and exercise (Elliott, Seals, and Jacobson, 2007; Fuzhong, Fisher, Harmer, & McAuley, 2005; Shin, Hur, Pender, Jang, & Kim, 2006). As the nature of behaviors of interest become more chronic and difficult to maintain, self-efficacy may emerge as a crucial component of the HBM.

The personal and economic costs of osteoporosis and fragility fractures are high. Considering that older age is one of the major risk factors for fragility fracture and the proportion of older Americans is increasing, reducing the risk for fragility fracture is imperative. The goal of OP research should be to improve understanding of the gaps in knowledge, perceptions, and beliefs and to, ultimately, affect health behavior change for better bone health.

This study is a cross sectional cluster analysis of data that was be gathered as part of an osteoporosis education intervention in the Alabama Medicare (Alacare) population. Alacare Home Health and Hospice is a Medicare-certified home health agency based in Birmingham, Alabama (Alacare Home Health & Hospice, 2011). Patients in home health care must be homebound, under the care of a doctor and require services such as intermittent skilled nursing care, physical therapy, speech therapy or continued occupational therapy (Department of Health and Human Services, 2010). Many studies in

osteoporosis and older adults have been done in the free-living, healthy population or in nursing home patients, not in the home-bound population receiving home health care. The home health population is more likely than the free-living healthy population to have multiple co-morbidities and is at high-risk for osteoporosis and fragility fractures. According the Surgeon General's report on Bone Health and Osteoporosis, 2.25 million home health care visits in 1995 were due to osteoporotic fractures (DHHS, 2004). Despite the high prevalence of fragility fracture in the home health population, these patients are often overlooked when it comes to diagnosis and treatment (Warriner et al., 2009). However, the home-health population presents a unique opportunity for education and follow-up since they have regular contact with health care professionals for some time.

The survey used in this study included data based upon the Osteoporosis Health Belief Scales. The following domains will be used: perceived OP susceptibility, perceived OP severity, perceived benefits of calcium supplements, perceived barriers to calcium supplements, perceived benefits of vitamin D supplements, perceived barriers to vitamin D supplements, perceived benefits of OP medications, perceived barriers to OP medications, self-efficacy for OP medications (which includes dietary supplements), and OP knowledge. The survey also included questions on OP medication adherence, calcium intake from foods, calcium supplement, vitamin D supplement, and multivitamin use.

The specific aims of this dissertation study are to use the data from the preintervention survey to determine if:

> participants in an osteoporosis education intervention study can be segmented into subgroups of similar individuals based on responses to the

Osteoporosis Health Belief Model, including measures of self-efficacy, as the underlying framework;

 associations exist between the defined subgroups and calcium supplement use, multivitamin use, vitamin D supplement use, and intake of high calcium foods.

The results of this study will add to the body of literature that will enable OP researchers to better assess learning and motivational needs of OP patients and those at risk for OP and develop behavioral interventions that will improve bone health and reduce the risk of fragility fracture

CHAPTER 2

REVIEW OF THE LITERATURE

Osteoporosis: The Importance of Diagnosis and Treatment

Osteoporosis is a skeletal disease characterized by low bone mineral density (BMD) and deterioration of bone micro-architecture, increasing the risk of fragility fractures (National Osteoporosis Foundation, 2010). In the U.S., an estimated 10 million people have osteoporosis and an estimated 34 million have low bone density and are at risk for developing osteoporosis and suffering a fragility fracture (National Osteoporosis Foundation, 2010). An estimated 1.5 million fragility fractures occur each year (Holroyd, Cooper, & Dennison, 2008). Between 30% and 50% of American women will have an osteoporosis-related fracture during their lifetime due to the effects of estrogen deficiency on bone mineral density (BMD; Cummings & Melton, 2002).

Fragility fractures contribute to morbidity and mortality in the older population and to a decreased quality of life (Cummings & Melton, 2002; Fraser, 2004; Hallberg et al., 2004; Huntgens et al., 2010). Researchers surveyed the health-related quality of life (HRQL) of postmenopausal women at a median of 82 days after a fracture and again after 2 years (Hallberg et al., 2004). After the first survey, HRQL was significantly reduced on all domains for vertebral and hip fractures and on several domains for forearm and humerus fractures. After 2 years, quality of life measures were normal for forearm and humerus fractures but still below normal on several domains for hip fractures and on all domains for vertebral fractures. The presence of one fragility fracture is a strong predictor of future fragility fractures. One study found that the risk of non-vertebral fractures was highest during the first year following an initial non-vertebral fracture (Huntgens et al., 2010). While fragility fractures secondary to low BMD are particularly concerning, researchers have found that both fragility and traumatic fractures are associated with low bone mineral density in older adults (Mackey et al., 2007).

All fragility fractures increase morbidity, however, hip and vertebral fractures also lead to increased mortality (Holroyd, Cooper, & Dennison, 2008). Kado et al. (1999) found a 1.23-fold increase in mortality among women age 65 and older with one or more vertebral fractures compared to women with no fractures. Mortality increased with increased numbers of vertebral fractures. The mortality rate among women with no fractures was 19 per 1000 woman-years to 44 per 1000 woman-years for women with five or more vertebral fractures. Mortality related to fractures was primarily due to an increased risk of cancers and pulmonary disease.

Researchers followed 6459 women age 55-81 for 3.8 years in the Fracture Intervention Trial and found that a total of 122 women died during the study with 23 deaths occurring after a clinical fracture (Cauley, Thompson, Ensrud, Scott, and Black, 2000). The age-adjusted relative risk of dying following any fracture was 2.15 (95% CI = 1.36-3.42). The relative risk of dying after a hip fracture was 6.68 (95% CI = 3.08-14.52) and for vertebral fracture was 8.64 (95% CI = 4.45-16.74).

In a five-year observational cohort study, Ioannidis and colleagues found that women who had vertebral fractures were 3.7 times more likely to die (95% CI = 1.2 - 8.1) than women who had not fractured (2009). Women with hip fractures were 3.0 times more likely to die than women who did not have a hip fracture (95% CI = 1.0 - 8.7). While the large confidence intervals make these results questionable, other studies support these findings. A ten-year population based study by Hasserius and colleagues found that prevalent vertebral deformity indicative of vertebral fractures predicted mortality over the following ten years (HR 2.4, 95% CI = 1.6-3.9 in men; HR 2.3, 95% CI = 1.3-4.3; Hasserius, Karlsson, Nilsson, Redlund-Johnell, & Johnell, 2003).

In a large, prospective cohort study, both older men and women who suffered from low-trauma fractures of several types were found to have increased mortality (Bliuc et al., 2009). Hip fractures were most predictive of death with a standardized mortality ratio of 2.53 (95% CI = 2.04-3.13) for women and 3.52 (95% CI = 2.58-4.80) for men. The mortality risk after vertebral fracture was, for women and men respectively, 1.76 (95% CI = 1.43-2.17) and 2.26 (95% CI = 1.72-2.98). The risk of death increased for major and minor fractures as well.

Fractures are an economic burden as well, costing an estimated \$19 billion in 2005 (National Osteoporosis Foundation, 2010). Researchers estimate that the cost of fragility fractures will rise to \$25.3 billion by 2025 (Burge et al., 2007). Gabriel et al. (2002) evaluated the direct medical costs of fractures in people age 50 years and older in a matched pair cohort study. The median direct cost for cases with and without fracture was \$761 and \$625 in the year prior to fracture. The year after the fracture, the cost was \$3884 for the fracture case and \$712 for the non-fracture control. Distal femur and hip fractures represented the highest median cost at \$11,756 and \$11,241 respectively.

Despite its high personal and health care costs, there is evidence that osteoporosis is often undiagnosed, even following fragility fracture. Many at-risk patients are unaware of their risk for osteopoporosis and fragility fractures and that effective treatments exist that can lower fracture risk (Backett-Milburn et al., 2000; Giangregorio et al., 2008;

Meadows et al., 2004). The National Osteoporosis Risk Assessment concluded that almost half of undiagnosed postmenopausal females age 50 and older had low bone mineral density (Siris et al., 2001). Of those with undetected low bone mineral density, 7% had osteoporosis. Giangregorio et al. (2006) described "the osteoporosis care gap" in a meta-analysis of 35 studies. They found that 1 to 45% of patients with fragility fractures received a diagnosis of osteoporosis. Calcium and vitamin D were recommended in 2% to 62% of patients and bone medications in 1% to 65% of patients. Recognition of risk factors by both practitioners and the public may be an important first step in the diagnosis and initiation of treatment.

Fractures in the older population are clearly burdensome both personally and economically. Given that fragility fractures occur at a higher rate in the elderly, the most rapidly growing segment of the population, identification of risk factors and proper diagnosis are essential. Since a variety of medications and behavioral approaches are available for the effective treatment of osteoporosis and fracture risk reduction, treatment is a reasonable goal.

Osteoporosis Risk Factors

Risk factors for osteoporosis and subsequent fragility fractures are numerous and are predictive of OP and fragility fracture risk (National Osteoporosis Foundation, 2010). Using nine population-based studies, Kanis et al. (2007) found that clinical risk factors alone were highly predictive of fracture risk. History of fractures, female gender, older age, heredity, low body weight, Caucasian and Asian ethnicity, and low estrogen/testosterone levels are risk factors over which patients have little or no control. Lifestyle risk factors that increase the risk of OP and fragility fractures include: physical inactivity, smoking, and dietary factors such as low calcium intake, low vitamin D intake/production, and excessive intakes of protein, sodium, alcohol, and caffeine. Education programs often promote lifestyle changes for the prevention and treatment of osteoporosis.

Postmenopausal females are at particularly high risk for osteoporosis and fractures due to advanced age, gender, and low estrogen levels. Advanced age is strongly associated with increased fracture risk due to its strong correlation with both decreased bone mass and possibly compromised bone architecture (Hannan, Felson, Dawson-Hughes, & Tucker, 2000). Low estrogen levels are associated with low bone mass due to increased bone resorption and decreased calcium absorption (Heshmati et al., 2002). However, low estrogen levels may increase fracture risk independent of the effects on bone mass. Cummings and colleagues found that women aged 65 and older with low serum estradiol levels, defined as < 5 pg/mL, were at increased risk of both hip and vertebral fractures independent of bone mineral density (BMD; Cummings et al., 1998). Hyperparathyroidism is also strongly associated with the risk of hip fracture in elderly women independent of BMD (Cummings et al., 1995).

Osteoporosis and the subsequent increased risk fracture are strongly associated with aging in both men and women. However, the prevalence of low bone mass is lower in men than in women. The age of men with primary osteoporosis is generally younger than that of women as well.

The Roles of Calcium and Vitamin D Supplementation in Bone Health

Adequate intakes of calcium and vitamin D are mainstays of bone health in older patients with or at risk for osteoporosis. Calcium plays a structural role in bone and acts as a reservoir to maintain serum calcium concentrations. Calcium makes up about 60% of bone mineral with phosphorus making up the other 40% (Weaver & Heaney, 2006). Hence, phosphorus is as important as calcium in bone mineralization. However, calcium receives more attention because phosphorus is ubiquitous in the diet while calcium sources are much more limited resulting in greater dietary deficiency. Extracellular and intracellular calcium play an important role in muscle contraction and relaxation, nerve functioning, blood clotting, and blood pressure. Parathyroid hormone responds to low plasma levels of calcium by increasing bone resorption. Because blood levels of calcium do not reflect dietary and supplemental intake, it is important to assess accurately a patient's intake via a thorough diet history (Weaver & Heaney, 2006).

Vitamin D mediates the active transport mechanism of calcium absorption in the intestine, increases calcium resorption in the kidney, and strengthens muscles hence, and possibly reducing falls and fractures. Inadequate vitamin D status is a cause of secondary hyperparathyroidism and can result in excessive bone resorption and elevated serum calcium levels (Holick, 2006). Despite the known functions of calcium and vitamin D in bone metabolism, the efficacy of vitamin D and calcium supplements in preventing and treating osteoporosis and in preventing fractures in older adults remains equivocal. However, growing evidence supports vitamin D supplementation for reducing the risk of falling and in fracture prevention.

Calcium and Vitamin D Requirements in Older Adults

While the role of calcium in bone health is generally accepted, controversy and uncertainty exist regarding appropriate recommendations (Prentice, 2002). For instance,

in the United Kingdom, recommendations are 700 mg a day for adults over the age of 50. This is considerably lower than recommendations in the U.S.

The Institute of Medicine (IOM, 2010) recently updated its recommendations for calcium and vitamin D intakes. The recommended dietary allowance (RDA) is 1200 mg of calcium a day for women over the age of 50 and 1000 mg a day for men over the age of 50 (Institute of Medicine, 2010). Higher calcium recommendations for older women reflect reduced fractional calcium absorption that occurs with age (Nordin, S.M., Need, A.G., Morris, H.A., O'Loughlin, P.D., & Horowitz, M., 2004). In post-menopausal women, fractional absorption is also reduced by lowered estrogen levels, increased resistance to 1,25(OH)D, and possibly decreased stomach acid (Nordin et al., 2006; Pattanaungkul et al., 2000; Recker, 1985). The tolerable upper level for calcium intake is 2,500 mg day for adults up to age 50 and 2,000 IU's a day for adults 51 years and older.

Recent research suggests that calcium recommendations are dependent upon vitamin D status and that higher calcium intakes may only be beneficial when serum levels of 25(OH) D are inadequate. Using NHANES III data, Bischoff-Ferrari et al. (2009) found that among women with higher serum vitamin D levels (> 50nM), a calcium intake above the lowest quartile (> 566 mg/day) was not associated with higher BMD. Higher calcium intakes were only associated with higher BMD in women whose serum 25(OH)D was < 50 nM.

While dietary sources can provide a significant amount of the recommended intake of calcium, many older Americans are not meeting their calcium needs through foods and beverages. Data from the National Health and Nutrition Examination Survey (NHANES) 1999-2000 found the average dietary calcium intake for women over age 60 years was 660 mg and 797 mg for men age 60 (Ervin et al., 2004).

The most recent NHANES (2003-2006) data also showed that older adults were not meeting their calcium needs (Bailey et al., 2010; Mangano, Walsh, Insogna, Kenny, & Kerstetter, 2011). The researchers assessed current dietary and supplement intakes of calcium using 24-hour recalls and a supplement use questionnaire. Among the participants, 43% reported using calcium supplements and 37% reported taking vitamin D supplements. The median dietary intake of calcium for women 81 years of age was the lowest at 603 mg \pm 33.0. However, none of the adults age 51 or older was meeting calcium recommendations even among those who reported taking calcium supplements. Males and females \geq 71 years of age and females age 14 to 18 years old were least likely to report intakes of calcium that were at recommended levels.

Typical dietary sources of calcium include milk, cheese, yogurt, and fortified products such as calcium-fortified orange juice and soymilk. Calcium per serving of foods and beverages considered as good sources ranges from 200 mg to 400 mg (Pennington, Bowes, & Church, 1998). Patients would need to eat and drink at least three to four servings of high calcium products each day to achieve their daily needs through dietary sources. To achieve adequate intake, many older adults require supplements if they are unable or unwilling to increase their intake of high calcium foods and drinks.

Current Institute of Medicine (IOM; IOM, 2010) vitamin D recommendations for adults up to 70 years of age are 600 IU's a day and 800 IU's for adults older than 70 years of age. The tolerable upper level for adults is now 4,000 IU's. These increased levels reflect the consensus among many vitamin D researchers that previous recommendations were too low and higher levels of vitamin D are necessary to achieve optimal serum status, achieve optimal calcium absorption, and prevent falls and fractures. However, some researchers recommend still higher levels. Recent research suggests that

an adult daily intake of 1000 IU's of vitamin D or greater is necessary to achieve adequate serum levels (Prentice, 2002; Vieth et al., 2007).

Naturally-occurring dietary sources of vitamin D are limited to fatty fish such as salmon, mackerel, herring, and cod liver oil. Fortified cereals, milk, and soymilk are also dietary sources of vitamin D; however, they are fortified up to only 100 IU's per serving (Institute of Medicine, 1997). Dietary supplements are also a source of vitamin D. Most multivitamin contain 400 to 1000 IU's per tablet. Calcium plus vitamin D tablets typically contain 200 to 500 IU's of vitamin D per serving. Vitamin D supplements are available in ranges of 400 to 2000 IU's per tablet.

The Efficacy of Calcium and Vitamin D Supplementation in Improving Bone Density and Fracture Prevention

Research findings regarding the efficacy of calcium and vitamin D in the prevention and treatment of osteoporosis are mixed. Most research supports nutrition and exercise for increasing bone density in childhood and early adulthood (Lorentzon, Mellstrom, & Ohlsson, 2005). However, the increase in bone turnover that comes with age is the major cause of osteoporosis in the older population and reduces the ability of calcium and vitamin D to maintain bone density. Varying methodologies, dosing regimens and levels, compliance, and outcome variables across the body of research also confound the issue.

In an 18 month randomized controlled trial, Chapuy et al. (1992) examined the effects calcium (1200 mg) and vitamin D3 (800 IU's) supplementation on the risk of hip fractures in 3270 women with a mean age of 84 years. For the women who completed the trial, the number of hip fractures was 43% lower in the supplemented group compared to

placebo (p = .043). The researchers reported similar results with intention-to-treat analysis.

In a 3-year randomized controlled trial, men and women who received 500 mg of supplemental calcium and 700 IU's of supplemental vitamin D experienced reduced bone loss in the femoral neck, spine and total body compared to participants in the placebo group (Dawson-Hughes, Harris, Krall, & Dallal, 1997). Of the 398 participants, 37 subjects had non vertebral fractures over the three year study period. A statistically significantly greater number of these fractures occurred in the placebo group (n = 26) when compared to the study group (n = 11; p = .02).

Other studies support that when participants are compliant with taking calcium and vitamin D supplements, the results are often positive. The Women's Health Initiative randomized women to a placebo group or a study group that received 1000 mg of calcium as calcium carbonate and 400 IU's of vitamin D (Jackson et al., 2006). The study group had statistically significant but small improvements in hip bone density (1.06%; *p* < .01) but no reduction in hip fractures in an intention to treat analysis. However, when researchers censored data from women who were non-adherent, the hazard ratio for hip fracture dropped to 0.71 (95% CI = 0.52-0.97). In light of recent data on optimal intake levels of vitamin D, a criticism of this study is that the level of vitamin D supplementation was unlikely to increase serum vitamin D to optimal levels.

The problem of non-compliance with calcium supplementation has led some researchers to conclude that advising patient to take calcium supplements is an ineffective strategy for the prevention and treatment of osteoporosis. In one study, researchers randomized women over the age of 70 (n = 1510; mean age = 75) to the study group (600 mg calcium carbonate twice daily) or placebo (Prince, Devine, Dhaliwal, & Dick, 2006).

Calcium supplementation did not significantly reduce fractures in the intention-to-treat analysis (HR = 0.87; 95% CI = 0.67-1.12). However, when the researchers analyzed 830 participants who took 80% or more of their tablets, the hazard ratio fell to 0.66 (95% CI = 0.45-0.97). The supplemented group also had improved bone strength when compared to the placebo group. A criticism of this study is that the study group did not receive vitamin D. The researchers measured serum 25-OHD levels in a sub-group of participants and determined that the majority were in the normal range. However, they defined normal as > 12 ng/ml while most vitamin D experts define normal levels as \geq 32 ng/ml (Vieth et al., 2007).

In a meta-analysis of randomized clinical trials, calcium alone or calcium/vitamin D supplementation was associated with a 12% reduction in fracture in the 17 studies that reported fracture as an outcome (RR = 0.88; 95% CI 0.83-0.95; p = 0.0004; Tang, Eslick, Nowson, Smith, & Bensoussan, 2007). However, fracture reduction doubled to 24% in trials when compliance reached a rate of 80%. Sub-analyses also showed greater fracture reduction in participants age \geq 80 years (24% reduction), in those whose calcium intake was \geq 1200 mg a day (20% reduction), and those whose vitamin D intake was \geq 800 IU's a day (16% reduction). Participants whose dietary calcium was low also had greater reductions in fracture risk (20%). In the 23 trials that reported bone loss, supplementation was associated with a 0.54% reduction in bone loss at the hip (0.35-0.73; p < .001) and a 1.19% reduction of bone loss at the spine (0.76-1.61%; p < .001).

In another meta-analysis of randomized clinical trials of calcium-only supplementation, researchers evaluated five studies comparing calcium supplementation (800 to 1600 mg a day) with placebo in people with and without non-vertebral fractures (Bischoff-Ferrari et al., 2007). No association between calcium supplementation and

fracture was found (RR = 0.92; 95% CI = 0.81-1.05). Four of the studies evaluated separate results for hip fracture and found no association between calcium supplementation and hip fracture with a possible slight increased risk for hip fracture (RR = 1.64; 95% CI = 1.02-2.64). The authors concluded that calcium supplementation without concomitant vitamin D supplementation is not advisable as osteoporosis therapy.

Vitamin D's role in calcium absorption via active transport is well known. However, vitamin D may play other roles in the prevention and treatment of osteoporosis. Recent research supports the role of vitamin D in reducing the risk of falling via increased muscle strength and in improving the outcomes of medication use (Barone, et al., 2007; Dhesi et al., 2002; Mowé, Haug, & Bohmer, 1999). Much of the research in this area supports vitamin doses higher than previously recommended.

New findings about the role of vitamin D in muscle strength have expanded our understanding of its function in fracture prevention beyond that of calcium homeostasis. When 1,25(OH)D binds to the receptor in the muscle tissue, it promotes protein synthesis, muscle cell growth, and muscle function. Blood levels of 25(OH)D are associated with muscle strength, physical activity, the ability to climb stairs, and fewer falls among the elderly (Dhesi et al., 2002; Mowé, Haug, & Bohmer, 1999).

Blake et al. (1988) found that the main risk factor for falls in people age 65 and over was muscle weakness. However, researchers have used doses that vary widely across studies leading to inconsistent results. Many researchers suggest that doses higher than 400 IU's a day are likely necessary to achieve positive outcomes. No benefit was found for 400 IU's of supplemental vitamin D daily for the prevention of fractures in a randomized controlled trial of 2578 participants 70 years or older (Lips, Graafmans, Ooms, Bezemer, & Bouter, 1996). Researchers randomized participants to receive either

placebo or 400 IU's of vitamin D3 daily for 3.5 years. In the vitamin D group, 48 people had a hip fracture; 58 people in the placebo group had hip fractures (p = .39). Older people living in residential care randomized to an initial dose of 10,000 IU's vitamin D weekly and then 1000 IU's daily for 2 years had a 0.73 (95% CI = 0.57-0.95) incident rate ratio for falling compared to the placebo group in the intention to treat analysis (Flicker et al., 2005). Their odds ratio for ever fracturing was 0.69 (95% CI = 0.40-1.18) compared to placebo. Subgroup analysis of those who reported taking at least half of the prescribed tablets had an incident rate ratio for falls of 0.63 (95% CI = 0.48-0.82) and an odds ratio of ever fracturing of 0.68 (95% CI = 0.38-1.22).

Other studies support the use of vitamin D supplementation to prevent falls and fractures. In a randomized, placebo-controlled double-blind trial, participants received 10,000 IU's of vitamin D2 (ergocalciferol) once a week and 1,000 IU's daily or placebo for 2 years (Flicker et al., 2005). In an a priori subgroup analysis, participants who took at least half the prescribed capsules had an incident rate ratio for falls of 0.63 (95% CI = 0.48-0.82) and an odds ratio for ever falling of 0.70 (95% CI = 0.50-0.99).

Broe et al. (2007) examined the effects of vitamin D supplementation on falls in 124 nursing home patients (mean age = 89 years) over a five-month period. Participants were randomized to one of five groups: placebo, 200 IU's, 400 IU's, 600 IU's, or 800 IU's of vitamin D daily. Participants in the 800 IU group had a 72% lower adjusted-incidence rate ratio of falls than those taking placebo over the 5 months (rate ratio = 0.28; 95% CI = 0.11-0.75). No significant differences were observed for the adjusted fall rates compared to placebo in any of the other supplement groups. The number of falls overall is striking with data showing that approximately 50% of nursing home residents fall at least once a year. Compliance in this trial was high at 97.6%. However, the sample size

was small and participants already taking multivitamin supplements continued taking them during the intervention so exact vitamin D intakes were hard to calculate. The researchers concluded that higher doses of vitamin D are necessary to achieve a reduction in falls. Since over 90% of hip fractures in the elderly occur after a fall, fall prevention should be a high priority in the treatment of osteoporosis.

After conducting a meta-analysis of double blind randomized controlled trials, Bischoff-Ferrari et al. (2005) concluded that vitamin D doses of 400 IU's did not prevent fractures. However, doses of vitamin D equal to 700 to 800 IU's reduced the relative risk of hip fracture by 26% in 3 trials (RR = 0.74; 95% CI = 0.61-0.88) and non-vertebral fractures by 23% (RR = 0.77; 95% CI = 0.68-0.87) in five trials. In an 18-year prospective analysis of calcium, vitamin D, and milk intake, women consuming greater than 500 IU's of vitamin D a day from food and supplements together had a 37% lower risk of hip fracture (RR = 0.63; 95% CI = 0.42-0.94) than women consuming less than 140 IU's D a day (Feskanich, Willett, & Colditz, 2003). Neither milk intake nor total calcium intake was associated with a lower risk of hip fracture.

Based on the growing evidence that vitamin D may reduce the incidence of falls, many osteoporosis researchers and clinicians recommend that all nursing home patients take vitamin D supplements. Unfortunately, an on-going problem is the successful implementation of fall and fracture prevention strategies in the nursing home setting (Colon-Emeric et al., 2007).

Many researchers have urged that greater attention to vitamin D supplementation at higher levels than are now recommended. In an editorial in the *Journal of Clinical Nutrition*, leading vitamin D/osteoporosis researchers recommended vitamin D intakes that raise serum levels to at least 75 nmol/L (30 ng/ml; Vieth et al., 2007). Barger-Lux

and colleagues recommend an additional intake of approximately 1700 IU's daily to raise 25(OH)D from 50 nmol/L to 80 nmol/L, which is considered to be optimal serum levels for bone health (Barger-Lux, Heaney, Dowell, Chen, & Holick, 1998). Older adults are at high risk for vitamin D deficiency, in part, because aging skin produces less 7-dehydrocholesterol, the precursor to vitamin D. Holick and colleagues compared young and older volunteers' responses to a single dose of UVB light (Holick, Matsuoka, & Wortsman, 1989). Young volunteers' levels of serum vitamin D went up to an average of 78 nmol/L (30 ng/ml) within 24 hours of UVB exposure. Older volunteers' levels went up to an average of 21 nmol/L (8 ng/ml) in the same time-period. The researchers concluded that a 70-year-old person exposed to the same amount of sunlight as a 20-year old makes ~25% of the vitamin D3.

Other data support the finding that sunlight is often an inadequate source of vitamin D for the elder population, particularly in northern latitudes (Webb, Kline, & Holick, 1988; Webb, Pilbeam, Hanafin, & Holick, 1990). The most recent NHANES data revealed widespread vitamin D deficiency among the general population. Overall, 1%-9% of the population had serum 25(OH)D levels < 27.5 nmol/L (11 ng/ml), 8%-36% had levels < 50 nmol/L (20 ng/ml), and 50%-78% had levels < 75 nmol/L (30 ng/ml; Yetley, 2008).

The prevalence of vitamin D deficiency, the lack of vitamin D in food sources, and the reduced capacity of older skin to make vitamin D, support the need for supplementation in the older population at risk for osteoporosis, falls, and fractures. Inadequate intakes of calcium through diet also support calcium supplementation in this at-risk population. However, persistence with calcium and vitamin D supplementation

appears to be a major hurdle in assessing the efficacy of calcium/D in preventing and treating osteoporosis.

Persistence is important to gain and maintain any positive effects from calcium /D supplementation. In a follow-up study after a 3 year randomized, placebo-controlled clinical trial of calcium/D supplementation, researchers found that supplement-induced bone mineral density increases in men were lost within 2 years of supplement discontinuation at the spine and femoral neck (Dawson-Hughes et al., 2000). Women experienced no lasting benefits after supplementation discontinuation at any site.

Many patients do not continue taking calcium and vitamin D over time. Giusti et al. (2009) surveyed 311 women age 70 and older who were discharged from an acute orthopedic ward post hip fracture with a prescription for calcium and cholecalciferol (vitamin D3). Six months after discharge, 114 patients (36.7%) were taking calcium/vitamin D supplements. Variables associated with supplement persistence were: absence of cognitive impairment (p < .001), use of six or fewer medications (p = .013), prescription of a bisphosphonate at discharge (p < 0.001), ability to walk without aid (p < 0.001), two or fewer active clinical issues (p = 0.005), discharged to home (p = 0.003), and a referral to a pre-planned osteoporosis physician visit (p < 0.001).

Other studies also show poor persistence with supplement use. In the previously discussed Women's Health Initiative, 59% of the study participants were taking 80% or more of their study supplements (Jackson et al., 2006). Prince et al. (2006) reported only 56.8% of the participants took 80% or more of their prescribed supplements per year in a five-year clinical trial of elderly women. Supplement adherence and persistence should be addressed both in research interventions and in the clinical setting to maximize the benefits of calcium and vitamin on bone health. High-risk populations, such as patients in

nursing homes and in home health care are particularly vulnerable to osteoporosis and fragility fracture.

The Home Health Care Population

Home health services meet the needs of patients who require specialized health care services but do not need the services of assisted living or skilled nursing facilities. To qualify for home health care, patients must be homebound, under the care of a doctor and require services such as intermittent skilled nursing care, physical therapy, speech therapy or continued occupational therapy (Department of Health and Human Services, 2010). Few studies examining osteoprotective behaviors have been conducted in the home health care population.

As of 2008, approximately 7.6 million people were receiving community-based health care for a variety of illnesses and disabilities (National Association for Home Care & Hospice, 2008). As the American populace continues to age, people in need of home health care will increase. The Department of Health and Human Services estimates that by 2050, 27 million people will need long-term health care, the majority of which receive that care within her or his community (2003).

Most of the patients using home health services are over 65 years of age and have several co-morbidities (Kirby & Lau, 2008; National Home Health and Hospice Care Survey, 2000). In 2007, home health patients had an average 4.2 diagnoses for each patient (Caffrey, Sengupta, Moss, Harris-Kojetin, & Valverde, 2011). Posthospitalization fracture care is responsible for over 2 million home health care visits a year in the United States (Department of Health and Human Services, 2006).

Poor nutritional status and low body weight are risk factors for osteoporosis. The nutritional status of the home health population is often compromised. Frail older adults (age \geq 65 years) in an urban setting were evaluated for BMI, serum albumin, and oral health problems (Ritchie et al., 1997). Twenty-nine percent of the women and 37% of the men were underweight (defined as a BMI < 24). Low serum albumin was present in 19% of the participants and 38% were not eating enough protein and calories. Poor oral health was associated with lower BMI's. More recent studies support these earlier findings. In an assessment of older home health patients' eating behaviors and the factors that affected their eating behaviors, researchers found that 70% of the participants were not eating enough calories to maintain their present body weight (Locher et al., 2008).

Medication adherence is also poor in the home health population. Gray and colleagues examined both under- and over-adherence to medications during a two week period following hospital discharge in patients receiving home health care (Gray, Mahoney, & Blough, 2001). Approximately 30% of the patients were under-adherent for at least one medication and approximately 18% were over-adherent for at least one medication.

Most studies focus on the prevalence of osteoporosis and osteoporosis treatment in the nursing home population or in the non-homebound community living population. Warriner et al. recommend treatment with osteoporosis medication, calcium, and vitamin D of older adults in the nursing home and home health settings after an initial fracture even in the absence of a diagnosis via a DXA scan (2009). However, despite the high risk of osteoporosis and fragility fractures, treatment is often overlooked according to the researchers. Many high risk patients are unaware of their risk and do not take practical, easily available steps, such as taking calcium and vitamin D, to reduce their risk.

Home health caretakers may be able to play an important role in improving medication compliance and the nutritional status of the home health population. Owens conducted a four-week intervention to determine if the caring behaviors of home health nurses influenced medication adherence in home health patients (2006). Verbal and nonverbal caring behaviors were found to improve medication adherence and to reduce adherence barriers. Locher and colleagues found that the presence of other people both generally in the household but also specifically at meals improved caloric intake in homebound older adults (Locher, Robinson, Roth, Ritchie, & Burgio, 2005). The researchers interviewed 50 older adults receiving home health care due to a recent acute illness or worsening of a present chronic condition. They found that participants who ate meals in the presence of another person ate an average of 114 calories more per meal than those who ate alone.

The home health care population is particularly vulnerable to osteoporosis and subsequent fractures due to both their often advanced age, the presence of several comorbidities, the presence of a fragility fracture, poor medication adherence and poor nutritional status. They also present an opportunity for appropriate intervention and assistance by the home health caretaker to improve their adherence to medications and nutritional status and possibly reduce the risk of subsequent fragility fractures.

Osteoporosis Knowledge, Beliefs, and Attitudes

Long-term change in health behaviors is often challenging for both the healthcare professional and the patient alike. Improving knowledge, health beliefs, attitudes, and personal risk assessment are widely believed to improve health behaviors. Incorrect assessment of personal risk and knowledge about chronic diseases often lead to an overestimate or underestimate of personal risk for various chronic diseases hindering appropriate behavior changes (Covello & Peters, 2002). For prevention and treatment of osteoporosis, getting enough calcium, vitamin D, exercise, and often the inclusion of osteoporosis medications are the hallmarks of osteoporosis prevention and treatment (NIH, 1994; Wolf et al., 2000). However, many people are unaware that osteoporosis is treatable and lack an accurate understanding of their personal risk for both osteoporosis and fragility fractures.

Similarly to other non-symptomatic chronic diseases, adherence and compliance among patients prescribed oral bisphosphonates are poor, reducing the efficacy of the medication (Caro, Ishak, Huybrechts, Raggio, & Naujoks, 2004; Clowes, Peel, & Eastell, 2004). Watts and colleagues found that 48% of patients in a managed care claims database did not fill a second prescription (Watts, Worley, Solis, Doyle, & Sheer, 2004). However, Roughead et al., (2009) found a duration-of-use that met minimum treatment requirements of 66% in existing users using data from the Department of Veterans' Affairs.

Several researchers have found that patients' attitudes and beliefs may be predictive of the use of certain osteoporosis medications. Cline and colleagues found that constructs of the health belief model were predictive of the adoption of newer bisphosphonates (Cline, Farley, Hansen, & Schommer, 2005). They found that higher perceptions of osteoporosis susceptibility (OR 1.34, 95% CI 0.55-0.77), high perceptions of benefits of osteoporosis medications (OR 1.34, 95% CI 1.10-1.63) and low perceived barriers to osteoporosis medications (OR 0.51, 95% CI 0.38-0.67). In a qualitative study, Unson and colleagues found that women's beliefs about medication safety, treatment

necessity, treatment cost, and treatment goals were related to treatment choice and adherence (Unson et al., 2003).

While knowledge of and awareness about a disease state are often first steps in behavior change intervention, they alone may not predict perceptions of personal risk or behavior change. In a series of semi-structured interviews with 15 older adults, Burgener and colleagues found that participants recognized the term "osteoporosis" but their understanding was incomplete (Burgener et al., 2005). The researchers also found that, while all of the participants viewed osteoporosis as a serious disease, many of them did not view themselves as personally as risk for developing osteoporosis. Personal experiences and the experiences of others can influence health beliefs and behaviors as well. For instance, one qualitative study revealed that women at mid-life who had health experiences (e.g. breast cancer) that increased the salience of osteoporosis, were more likely to be aware of their osteoporosis risk (Backett-Milburn et al., 2000). The researchers also found that women who had a friend or family member with osteoporosis were more aware of their risk. Conversely, women who had an older relative without osteoporosis or fractures were more likely to perceive themselves at low risk for the disease. Hsieh and colleagues also found discordance between disease beliefs and perceptions of personal risk (Hsieh, Novielli, Diamond, & Cheruva, 2001). In a convenience sample of 60 women age 40 to 95 years, they found that 89% believed osteoporosis is a serious condition; however, only 29% believed themselves to be at personal risk for the disease.

Other factors, such as gender, may also be associated with knowledge and health beliefs about osteoporosis. In a prospective cohort study of 145 senior men and women attending either a senior's clinic or a social day program (mean age = 76), 89% were

aware of osteoporosis and 61% gave the correct definition (Juby & Davis, 2001). However, only 33% believed that she or he "will get osteoporosis." Men were less likely to be aware of osteoporosis and give an accurate definition of it than women (77% vs. 94%; p < .01 and 44% vs. 67%; p < .05). Men were also less likely than women to believe that osteoporosis can affect men (54% vs. 83%; p < .001), is preventable (41% vs. 62%; p < .05), that diet is important (69% vs. 89%; p < .01), and that they would get osteoporosis (18% vs. 39%; p < .05).

The Health Belief Model

In the 1950's, a group of social psychologists developed the Health Belief Model (HBM) to explain why people failed to participate in free public programs to screen for diseases such as tuberculosis (Hochbaum, 1958; Rosenstock, 1974). Researchers found that people who believed they were susceptible to tuberculosis and that they would benefit from early detection were more likely to avail themselves of free screening chest X-rays (Hochbaum, 1958). It is important to note that the model was originally developed to predict health screening behaviors, a screening behavior specific to tuberculosis. Since that time, researchers have attempted to use the model in a variety of disease settings and have expanded its use to not only explain and predict behaviors but to change behaviors.

The HBM views the likelihood of behavior and behavior change as the result of the interplay among a person's perceived disease threat, cues to taking action and selfefficacy for the action, and a cost benefits analysis between perceived benefits and barriers for the recommended action (Janz et al., 2002; Figure 1).

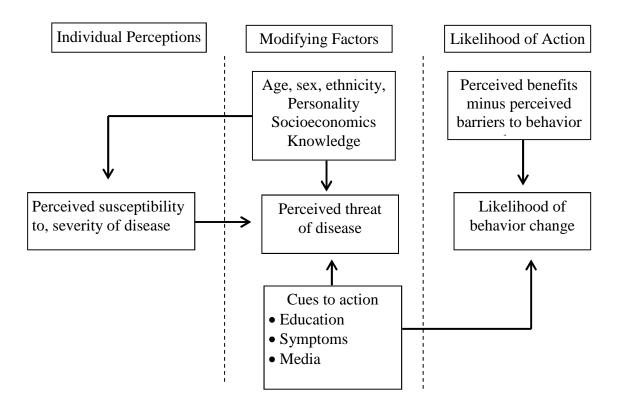


Figure 1. The Health Belief Model

The two central aspects of the health belief model are perceived threat and evaluation of the recommended behavior. The first aspect, perceived threat, is a combination of a person's subjective perception of his or her risk of developing a disease or a condition (perceived susceptibility) and his or her subjective perception of the severity or seriousness of contracting a disease or condition (perceived severity). Modifiers of perceived threat include demographic factors such as age, gender, ethnicity, socioeconomics, and knowledge, and cues to action such as education, symptoms, and media exposure.

The second aspect of the model focuses on a person's evaluation of a behavior. Behavioral evaluation is comprised of two beliefs: the benefits and/or the efficacy of the recommended health behavior and the barriers and/or costs of the recommended behavior. The HBM posits that if a person's perceptions of the benefits of the advised action outweigh the barriers and costs of taking the action, and if perceived threat is adequate, then a person will adopt the recommended behavior. The behavioral evaluation component is essentially a cost/benefit analysis.

Other modifiers of the model in include "cues to action" which may modify perceived threat or lead to direct action. Cues to action include knowledge, media campaigns, stories, and messages about the health risk and actions to take, a doctor's diagnosis and advice, and the symptoms of a disease or a disorder (Abraham & Sheeran, 2005; Janz et al., 2002).

Broadly, the health belief model can be used in three areas: preventive health behaviors, sick role behaviors, and clinical use in a physician's office (Abraham & Sheeran, 2005). Preventive health behaviors can be further categorized as healthpromoting, such as exercising and healthy eating and health-risk behaviors such as using condoms, getting vaccines, and smoking cessation. Sick role behaviors refer to adhering to specific regimens that improve a disease state, such as medication adherence and persistence.

Issues of operationalization, the assumption that the subscales are unidimensional, and issues of subscale validity and wording make the effective use of the model challenging and may explain the wide variety of results researchers have experienced when using the model (Abraham & Sheeran, 2005). The developers of the model did not specify how to operationalize each of the constructs. For instance, there is no specific "formula" for how benefits and barriers are weighted against one another. Tversky and Kahnean (1981) found that changes in the wording of the subscales had effects on responses and stressed the importance of multi-item scales.

Some researchers have drawn particular attention to the operationalization of susceptibility. The concept of susceptibility could mean several different things: the possibility of contracting a disease, the likelihood of getting sick, or the likelihood of disease recurrence (Becker & Maiman, 1975). In 1988, Weinstein proposed that susceptibility has three stages: awareness of a disease threat, how many people may be affected by the disease threat, and finally, a personalization of the threat. He suggests that only in this final stage of personalization is susceptibility acknowledged and accepted.

The multidimensionality of the other constructs also has been examined. Severity may mean pain, disease complications, psychosocial severity, or negative emotions. Researchers found that the construct of perceived severity of breast cancer depended upon if the breast cancer was treated promptly or if it was treated late (Ronis & Harel, 1989). The constructs of perceived benefits and barriers are also likely to be multidimensional in nature. For instance, benefits may be psychosocial, medical, or economic in nature. Barriers may be practical in nature (cost, time) or psychosocial (pain, embarrassment, or threatening to lifestyle; Abraham & Sheeran, 2005).

As more researchers began using the model, some became concerned with the lack of valid and reliable subscales being developed and the inconsistent application of the model across diseases and behaviors. Researchers have also found that the model as a whole is not always associated with behaviors and that some constructs are more relevant than others with certain behaviors and disease states. When Champion developed and tested an HBM instrument for breast self-exam, she found that severity, benefits, barriers, and health motivation were most predictive of the frequency of self-examination (1984). Generally, the construct of perceived barriers has been found to be more closely related to the likelihood of behavior change across all diseases and behaviors (Janz et al., 2002).

The HBM constructs also vary in their ability to predict behaviors depending upon the nature of the behavior. In sick-role behaviors, perceived benefits appears to be most important while perceived susceptibility is more predictive of preventive behaviors (Janz et al., 2002).

Despite these challenges, researchers have used the HBM as a conceptual framework for a variety of health behavior interventions. In 1984, Janz and Becker published a comprehensive review of use of the HBM as the theoretical basis of behavioral research (Janz & Becker, 1984). They recommended that researchers consider HBM constructs across a variety of health behaviors. The popularity of the HBM has led to numerous summaries and evaluations of its effectiveness.

The Osteoporosis Health Belief Scale

Clearly, researchers need to use and adapt the HBM to the specific disease and behavior of interest. The Osteoporosis Health Belief Scale (OPHBS) was adapted from the HBM and evaluated by Kim, Horan, Gendler, and Patel (1991). The 35-item survey consists of the following subscales: Osteoporosis Seriousness, Osteoporosis Susceptibility, Health Motivation, Calcium Benefits, Calcium Barriers, Exercise Benefits, and Exercise Barriers. Since its development, researchers have evaluated the OPHBS constructs as a framework for understanding osteoporosis health beliefs, predictors of bone health behaviors and as the basis for bone health interventions with varying degrees of success.

Jachna and Forbes-Thompson (2005) used the OPHBS to organize participants' responses from semi-structured interviews with older women in an assisted living facility and to make recommendations for message construction and osteoporosis education

protocols. They concluded that maintaining control and independence defined "health" for the participants. Overall, even though several of the participants had sustained a fragility fracture, most did not view osteoporosis to be as threatening (combined perceived severity and perceived susceptibility) as other health concerns. However, this was a very small exploratory study (n = 5) so the findings have limited applicability.

Cline and Worley also used the OPHBS in a cross sectional evaluation of 990 women to determine if the women could be segmented into meaningful clusters based on five subscales of the Health Belief Model: perceived susceptibility, perceived severity, perceived benefits of taking supplements, perceived barriers of taking supplements, and health motivation (Cline & Worley, 2006). They then tested the multivariate associations between cluster membership (independent variable) and over-the-counter-supplement (OTC) use (dependent variable).

The researchers found three distinct clusters. Cluster 1 was described as high susceptibility/high OTC use. Members in this cluster were more likely to have been tested for osteoporosis and very likely to report a diagnosis of osteoporosis in their mother or sister. Members in this cluster were less likely than members in the other two clusters to perceive osteoporosis as a serious disease. Cluster 2 was described as high threat/low OTC use. Members in this cluster reported that the perceived barriers to OTC use were higher than the perceived benefits. Cluster 2 members also scored the lowest on the general health beliefs subscale. Cluster 3 was described as low threat/high general health beliefs. Women in this cluster had low perceived susceptibility and low perceived severity of OP but scored the highest on general health beliefs when compared to the other two clusters. These women were likely to exercise, not to smoke cigarettes, and to

use soy supplements. As previously discussed, the researchers did not include selfefficacy as a construct of the model.

Using a cross-sectional mailed survey, Nayak, Roberts, Chang, and Greenspan used components similar to the OPHBS within the Extended Parallel Process Model to examine beliefs about osteoporosis screening in 1,830 women and men aged 60 years and older. The mean age of respondents was 73.3 years and 58.7% were female. The respondents reported stronger beliefs in severity compared to their beliefs in personal susceptibility to osteoporosis (p < .001). Older people were less likely to perceive osteoporosis as being severe when compared to younger people and women were more likely to view themselves as being susceptible to osteoporosis when compared to men. The researchers concluded that older people in this population exhibited several beliefs that may prevent them from seeking osteoporosis screening, including low perceived personal susceptibility to osteoporosis.

Some researchers have used the HBM as the basis of a clinical intervention to encourage behavior change. Using a pre-post-test design, Tussing & Chapman-Novakofski used a convenience sample of 42 women to evaluate an 8-week community education program based on self-efficacy, the HBM, and the Theory of Reasoned Action to increase calcium intake (2005). The researchers found statistically significant improvements for *benefits to increasing calcium intake, susceptibility to osteoporosis,* and three individual items of self-efficacy. No changes were found for barriers to increasing calcium intake, or items for *severity of osteoporosis.* Overall, the participants increased their calcium intake after the intervention (644 ± 383 mg/day vs. 821 ± 372 mg/day; p < .0001).

Hazavehei et al. (2007) found that a health education intervention based on the HBM was more effective than a didactic approach or no intervention in increasing calcium intake and level of physical activity in adolescent girls. The girls in the HBM group showed statistically significant improvements in knowledge, perceived susceptibility, perceived severity, perceived benefits, and perceived barriers when compared to the two control groups.

In a study designed to evaluate three HBM-based osteoporosis prevention programs of varying intensity, the researchers found that all of the programs were equally effective at increasing knowledge but none changed the participants' health beliefs or increased OP prevention behaviors (Sedlak, Doheny, & Jones, 2000). The researchers concluded that matching the materials to the stage of change of each participant may improve outcomes. Also, the demographics among each of these interventions differed greatly on age and other factors such as professional status. The number of participants in each group was relatively small, limiting the strength of the findings.

In a systematic review of studies that used the OPHBS in either descriptive or intervention studies, McLeod and Johnson found that of the 22 articles they reviewed, only 6 were intervention studies and only 8 included men (2011). The results of the descriptive studies showed that women tended to have higher perceived susceptibility, higher perceived benefits of calcium intake, fewer perceived barriers to calcium intake, and lower health motivation compared to men. They also found that men and women 45 years of age and older had greater perceived susceptibility, greater perceived seriousness, and greater perceived barriers to calcium intake and exercise when compared to men and women younger than 45 years. Self-efficacy for calcium intake was also higher in older adults than in younger adults. The researchers found that several of the interventions they

reviewed did show positive results; however, the lack of randomized controlled trials made it difficult for them to draw meaningful conclusions. Issues of small sample size, differing measures used in each study, and the fact that only one study included men made definitive conclusions difficult.

Differences in demographics, program design, stage-of-change, outcome construct in the model measures and level of tailoring may explain some of the differences in success of interventions using the OPHBS.

Self-Efficacy and the Health Belief Model

Self-efficacy originated as a construct within social learning theory. Bandura (1986) describes self-efficacy as a person's confidence in his or her ability to perform a specific task in a variety of settings and circumstances. According to Bandura, self-efficacy is behavior specific, not a general state of being or personality characteristic as with self-esteem. For instance, a person may feel confident in her ability to walk three times a week but not feel confident that she can change the way she eats. It can predict behaviors but also arise from behaviors. Self-efficacy is also linked to persistence and effort expended in taking the action. Therefore, when self-efficacy is integrated into the HBM, a behavior or a change in behavior is predicted when a person perceives a threat to health, the benefits of the recommended action outweigh the costs, there are effective cues to action, and the person has confidence in his or her ability to undertake the recommended action despite perceived barriers.

An aspect of self-efficacy that makes it practically useful in health behavior research is that self-efficacy can be improved using specific strategies (Grembowski et al, 1993). Performance accomplishments (learning through personal experiences), vicarious

experience (observing others who are similar to oneself performing the task or behavior), verbal persuasion (information from others expert in that particular area), and emotional arousal (information about the consequences and benefits of behaviors) are all methods of improving self-efficacy.

Studies of older women support self-efficacy as a predictor of exercise behavior. In a cross sectional study of Korean women over age 40, exercise self-efficacy accounted for 27% of the variance in commitment to a plan for exercise among women with osteoporosis and 53% of the variance among women with osteoarthritis (Shin, Hur, Pender, Jang, & Kim, 2006).

According to Rosenstock, Strecher, & Becker (1988), the omission of selfefficacy from the HBM may mean that the model has failed to account for as much variance in behavior as it might have with the inclusion of this construct. When the HBM was developed, researchers were interested in "one shot" behaviors such as screenings for disease or getting inoculations. However, long-term behaviors such as exercise and changing eating patterns—behaviors that are more difficult to attempt, develop, and maintain over time when compared to getting a vaccine or a screening. These difficult, long-term behaviors likely require a great deal of self confidence in one's skills and abilities to adopt and maintain the behavior. As researchers began to use the HBM for long-term behavior change, the value of adding self-efficacy to the model became apparent (Rosenstock et al., 1988).

While self-efficacy is now an accepted construct of the health belief model, researchers do not consistently include when using the HBM as the theoretical basis of their research. The study of self-efficacy in older adults specific to disease management has been limited but suggests that it may be an important factor in predicting and

changing health behaviors in older adults. Early studies showed that self-efficacy is likely to play a role in the exercise behavior of older adults (Gill, Kelley, Williams, & Martin, 1994; Sallis, Hovell, & Hofstetter, 1992; Sharpe & Connell, 1992).

Grembowski et al. (1993) hypothesized that older persons' efficacy and outcome expectations in one health behavior such as exercise would be positively correlated with efficacy and outcome expectations in other areas such as smoking and dietary fat intake. They also hypothesized that efficacy expectations would negatively associate with health risk, age, gender, and number of physician visits and positively associated with health and SES status. Results showed that efficacy and outcome expectations were not independent with two dimensions. The first dimensions consisted of exercise, dietary fat, weight control. The second dimension consisted of smoking and alcohol intake. Efficacy and outcome expectations were greater for people who were not at risk in each of the health behavior areas. While people with higher efficacy and outcome expectations reported better health status and fewer physician visits, the correlations were small.

Clark and Dodge (1999) explored self-efficacy and the prediction of heart disease management behaviors and also the factors associated with self-efficacy beliefs in medicine use, diet, exercise, and stress management in 570 women 60 years and older. The researchers found that baseline self-efficacy predicted behaviors in each of the four behaviors areas.

Elliott, Seals, and Jacobson (2007) used the precaution adoption process model to examine predictors of osteoprotective behaviors in women with a mean age of 45. They found that participants with higher self-efficacy for calcium were more likely to be in the maintenance stage for dietary calcium and for calcium supplements.

Other researchers have studied self-efficacy as a predictor of balance and mobility in older women with osteoporosis (Liu-Ambrose et al., 2006). They found that falls selfefficacy was independently associated with balance and mobility even after accounting for age and level of physical activity and that self-efficacy was more strongly associated with balance and mobility than were measures of physiological function. These results support Bandura's assertion that perceived self-efficacy is more predictor of physical activity than is physical capability (1984).

In McLeod and Johnson's systematic review of studies using the OHBS as their theoretical basis, the researchers found that, overall, self-efficacy scores for calcium intake and exercise were moderately high (2011). They also found that men and women age 45 and older tended to have similar self-efficacy scores for calcium intake but that men had higher self-efficacy for exercise compared to women.

Self-efficacy may be an important, yet underused, construct in predicting behaviors and may be an effective point of behavioral intervention. Researchers should include measures of self-efficacy when using behavioral models such as the health belief model and the social cognitive theory.

Conclusions

As the U.S. population ages, the number of people with osteoporosis and subsequent fragility fractures will continue to increase at great personal and national cost (Greendale, Barrett-Connor, Ingles, & Haile, 1995; Jordan & Cooper, 2002; Marottoli, Berkman, & Cooney, 1992; Ray, Chan, Thamer, & Melton, 1997). Public health and clinical efforts should focus on raising awareness that effective treatments that lower fracture risk are available. Efforts should focus on vitamin D supplement use of at least 1000 to 2000 IU's a day from OTC supplements since food sources are inadequate and sunlight exposure is not as effective in increasing vitamin D levels in older adults. Since many older American may find it difficult to meet their calcium needs through diet alone, appropriate calcium supplement use should also be taught. Medication adherence and persistence should be promoted in patients with prescriptions for osteoporosis medications. At risk-patients who have not been prescribed medications should be encouraged to discuss their risk with their physicians.

All education programs should be based on sound health behavior theory with behavior change as the major outcome of interest. The Osteoporosis Health Belief Model (Kim et al., 1991) has been used in many studies as the underlying behavioral framework to explain or change behavior. Continued research that links theoretical constructs with behavior change will help clinicians and educators to tailor materials based on patients' beliefs, attitudes, and perceptions and better achieve behavior changes that lower fracture risk and subsequent costs.

CHAPTER 3

RESEARCH DESIGN AND METHODS

Introduction

This study is an analysis of baseline data gathered as part of an osteoporosis education intervention study in the Alabama Medicare (Alacare) population. The goal of the parent intervention study is to determine if a written, tailored, theory-based intervention increases the number of people taking calcium and vitamin D supplements and taking prescribed osteoporosis medications properly. A survey instrument was developed (see Appendix A) to be delivered via Computer Administered Telephone Interview (CATI) before and four months after the written, tailored intervention materials are mailed to participants. The survey was designed to assess a variety of behaviors and beliefs including use of and adherence to osteoporosis medicine, reasons for stopping osteoporosis medicines, beliefs about osteoporosis, risk of fracture and lifestyle behaviors such as dietary intake of calcium and use of calcium and vitamin D supplements.

The theoretical basis for the pre- and post-intervention surveys and the intervention materials are the Health Belief Model and the Osteoporosis Health Belief Scales (Cadarette, Beaton, & Hawker, 2004; Kim et al., 1991). The results of this research will be published at a later date.

The Dissertation Study

The specific aims of this study are to use the data from the pre-intervention survey to determine if:

- participants in an osteoporosis education intervention study can be segmented into subgroups of similar individuals based on responses to the Osteoporosis Health Belief Model scales including OP medication self-efficacy.
- associations exist between the defined subgroups and calcium supplement use, multivitamin use, vitamin D supplement use, and intake of high calcium foods. self-efficacy for OP supplement adherence is associated with taking calcium and vitamin D supplements

The design of this dissertation study is a cross-sectional analysis. Variables of interest are based upon the Osteoporosis Health Belief Model domains: perceived osteoporosis susceptibility, perceived osteoporosis severity, perceived fracture severity, perceived benefits of calcium supplements, perceived barriers to calcium supplements, perceived benefits of vitamin D supplements, perceived barriers to vitamin D supplements, perceived barriers to vitamin D supplements, perceived barriers to osteoporosis medications, self-efficacy for osteoporosis medications (which includes dietary supplements), and osteoporosis knowledge. Data also was collected on three preventive behaviors: calcium intake from foods, calcium supplement use, and vitamin D supplement use.

Population

The participants were Alacare patients over 50 years of age with either a diagnosis of osteoporosis or a medical history of fragility fracture, or both. Alacare is privately owned, Medicare-certified home health agency based in Birmingham, AL. High risk of fracture was defined as: (a) a diagnosis of osteoporosis, (b) a medical history of fragility fracture, or both. Exclusion criteria are: (a) patients in hospice; (b) patients with a life expectancy of < 1 year; (c) patients > 95 years old; (d) patients having concomitant metabolic bone disease (such as Paget's disease).

Recruitment

Participant recruitment was conducted through 27 Alacare home health offices. Participants who had been diagnosed with osteoporosis or who had sustained a fragility fracture were referred to home health care. Participants were offered a \$20 gift card for completing the pre- and post-intervention surveys. The recruitment goal was a total of 150 for purposes of this study. UAB Institutional Review Board approved all recruitment activities.

Survey Development

The participant survey (see Appendix A) was based on several questionnaires already in existence and questions developed as part of the protocol for the parent study *Improving Osteoporosis Care in High-Risk Home Health Patients through a High-Intensity Intervention* at the University of Alabama at Birmingham.

The OPHBS instrument with revisions for telephone administration served as the basis of the survey's theoretical framework (Cadarette, Beaton, & Hawker, 2004; Kim,

Horan, Gendler, & Patel, 1991). Perceived osteoporosis susceptibility and perceived osteoporosis severity measures from this instrument were included. Four subscales were adapted from the original OPHBS and tested for reliability using Cronbach's alpha: perceived benefits of calcium supplement use, perceived barriers to calcium supplement use, perceived benefits of vitamin D supplement use, and perceived barriers to vitamin D supplement use. Self-efficacy for medication adherence, which included calcium and vitamin D supplements, were measured using the *Self-Efficacy Scale for Osteoporosis Medication Adherence* scale (Resnick, Wehren, & Orwig, 2003). The survey addresses participants' present use of calcium and vitamin D supplements, multivitamins, osteoporosis medications, and intake of high calcium foods. Measures are described below.

Measures

Demographic and Personal Characteristic Assessments

Demographic measures include age, gender, ethnicity, years of education. Diagnosis of osteoporosis, personal fracture history, family history of hip fracture, history of tobacco use, diagnosis of osteoarthritis, osteoporosis medication use, and body mass index (BMI) are also assessed.

Osteoporosis Health Belief Subscales

The perceived osteoporosis susceptibility and severity scales from Kim et al.'s (1991) Osteoporosis Health Belief Model Subscales with minor changes recommended for telephone administration by Cadarette et al. (2004) were used to measure participants' beliefs about the threat of osteoporosis. We adapted and evaluated four scales for within

scale reliability (Cronbach's alpha) and test-retest (Pearson *r*) reliability. The scales adapted from the OPHBS (Kim et al., 1991) were: (a) perceived benefits of and (b) perceived barriers to calcium supplement use and (c) perceived benefits of and (d) perceived barriers to vitamin D supplements.

The wording of the calcium and vitamin D supplement perceived benefits and barriers subscales was based on similar scales of Cadarette et al. (2004). We used a convenience sample of patients having had DXA scans in the UAB Osteoporosis Prevention and Treatment Clinic to conduct reliability testing on the subscales. We contacted patients who had indicated that UAB researchers could call them for study purposes and asked if they would like to participate in the subscale testing. We offered each participant a \$20 gift card for completing the test/retest questionnaires. See Appendix 3 for the script and questionnaire. Once a patient agreed to participate, we conducted the first survey. We conducted the second survey no fewer than 2 weeks after the first survey.

We made minor changes in the Kim et al. OPHBS for use in CATI. Resnick et al.'s (2003) self-efficacy for osteoporosis medication adherence scale was used to measure participants' self-efficacy for using osteoporosis medications and calcium and vitamin D supplements. The perceived benefits of and barriers to oral bisphosphonates subscales was used to measure participants' beliefs about the use of the most commonly used osteoporosis medications (Cadarette et al., 2004). All of these scales use a 5-point Likert response scale (Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree).

Perceived Susceptibility to Osteoporosis. The perceived susceptibility subscale is a 4-item scale and resulted in a Cronbach's alpha reliability coefficient of .88 for a sample of 425 women aged 61 to 93 years (Cadarette et al., 2004). The authors dropped

two items from the original scale due to redundancy. In the original OPBHM for the 6item subscale, the test-retest Pearson correlation coefficient was .84 (Kim et al., 1991).

Perceived Severity of Osteoporosis. The perceived severity subscale is a 6-item scale that required no changes from the original with a Cronbach's alpha of .74 for a sample of 425 women aged 61 to 93 years (Cadarette et al., 2004). In the original OPBHM, the test-retest Pearson correlation coefficient was .79 (Kim et al., 1991).

Perceived Benefits of Calcium Supplement Use. The perceived benefits of calcium supplement use was developed specifically for the education intervention study. It is a 6-item subscale that resulted in a Cronbach's alpha coefficient of .79 and a test-retest Pearson correlation coefficient of .57 for a sample of 43 adults aged 42 and older.

Perceived Barriers to Calcium Supplement Use The perceived barriers of calcium supplement use was developed specifically for the education intervention study. It is a 6item subscale that resulted in a Cronbach's alpha of .75 and a test-retest Pearson correlation coefficient of .92 for a sample of 30 adults aged 42 and older.

Perceived Benefits of Vitamin D Supplement Use. The perceived benefits of vitamin D supplement use was developed specifically for the purpose of this research. It is a 7-item scale resulting in a Cronbach's alpha coefficient of 0.71 and a test-retest Pearson correlation coefficient of 0.64 for a sample of 43 adults aged 42 and older.

Perceived Barriers to Vitamin D Supplement Use. The perceived barriers of vitamin D supplement use scale was developed specifically for the purpose of this research. It is a 6-item subscale resulting in a Cronbach's alpha coefficient of 0.78 and a test-retest Pearson correlation coefficient of 0.92 for a sample of 30 adults aged 42 and older.

Self-Efficacy for Osteoporosis Medication Adherence Scale, The self-efficacy for osteoporosis medication adherence scale evaluates the confidence a person has for taking osteoporosis medications, including calcium and vitamin D supplements. This 16-item Likert subscale resulted in a Cronbach's alpha coefficient of 0.98 in a sample of 152 adults aged 65 years or older. Confirmatory factor analysis showed that all of the items were related to the construct with 77% of the variance explained by the measure (Resnick et al., 2003).

Sample Size Considerations

According to Garson (2010), a sample size of fewer than 250 people is appropriate for two step cluster analysis. Data were collected over a 9-month period.

Statistical Analysis

The data were analyzed using SPSS Version 19 (2010). As a preliminary step, appropriate descriptive statistics including frequencies, percentages, means, and standard deviations, and were examined for outliers and missing data.

The variables used in the analysis for Specific Aim 1 are summarized in Table 1. To determine if participants in an osteoporosis education intervention study can be segmented into subgroups of similar individuals based on responses to the Osteoporosis Health Belief Model scales, we analyzed the data using the cluster procedure for two step cluster analysis. Cluster analysis is an exploratory statistical analysis that allows researchers to determine if naturally occurring groups or clusters exist in a data set. Cluster analysis can be used help researchers to summarize and classify data or as a way to create cluster prototypes to be used in further analysis such as predicting behaviors or who would benefit from particular interventions. Two-step cluster analysis is designed for both categorical and continuous variables.

Cluster analysis differs from other classification methods such as factor analysis and discriminant analysis in two key ways. Unlike factor analysis in which cases may be classified into more than one group, cluster analysis restricts a case to only one group. Also, cluster analysis identifies the actual groups a posteriori rather than the researcher identifying group memberships or the number of groups beforehand (Norušis, 2005).

The goal of cluster analysis is to create clusters (groups) that have good cohesion and separation. A good cluster solution yields clusters that have high cluster cohesion meaning that members within that cluster are closely related to one another on specific measured attributes. A good cluster solution should also yield clusters that have high separation meaning that different clusters are truly distinct from one another on specific measured attributes and that members in one cluster clearly belong in that group and not to another.

Historically, cluster analysis has been used in a marketing setting to segment audiences into smaller groups based on similar characteristics and as a basis to develop new products, sell existing products, and to determine the most effective distribution and communication strategies (Goldstein, 2007). Researchers and practitioners in the field of public health have adopted these strategies to use in public health to improve their understanding of how group membership may predict particular behaviors. Slater and Flora (1991) used cluster analysis based on patterns of health attitudes, social influences and behaviors to determine if group membership predicted behaviors such as eating less salt, exercise patterns, and losing weight. Many researchers have used cluster analysis to segment people in terms of their patterns of food choice (Newby & Tucker, 2004). Others

have used cluster analysis to assess the skills, knowledge, and practices of health care practitioners. Chan and Zang (2006) found that nurses could be segmented into three clusters based on their perceived diabetes knowledge and actual diabetes knowledge.

The following constructs from the health belief model were used in the analysis: OPHBM subscale scores, osteoporosis medication self-efficacy scores, and osteoporosis knowledge scores.

Table 1

Scale	Measure (mean score on a 5-Point Likert Scale)		
Perceived Susceptibility of OP-	4 items; Cadarette, et al. (2007)		
categorical	"High" > 3.0 or self-reported diagnosis of OP		
	"Low" ≤ 3.0		
Perceived Susceptibility of OP-	4 items; Cadarette, et al. (2007)		
continuous	Subscale mean		
Perceived Severity of OP	6 items; Kim, et al. (1991); Cadarette, et al. (2007)		
	Subscale mean		
Perceived Benefits of Calcium	6 items; adapted from Cadarette et al.(2007)		
Supplement Use	Subscale mean		
Perceived Barriers to Calcium	6 items; adapted from Cadarette et al.(2007)		
Supplement Use	Subscale mean		
Perceived Benefits of Vitamin D	7 items; adapted from Cadarette et al.(2007)		
Supplement Use	Subscale mean		
Perceived Barriers to Vitamin D	6 items; adapted from Cadarette et al.(2007)		
Supplement Use	Subscale mean		
Supprement Ose Self-Efficacy for Osteoporosis	16 items; Resnick et al, 2003		
Medication Adherence	Subscale mean		
meaication Aanerence	Subscale mean		

Initial Subscales Planned for Use in Two Step Cluster Analysis (Specific Aim 1)

The dependent variables used in the analysis for Specific Aim 2 are summarized in Table 2. After the cluster solution was determined from the two-step cluster analysis, we conducted a one way analysis of variance (ANOVA) on cluster solutions with three or more groups and independent *t*-tests on those with fewer than three groups to determine what, if any, mean differences exist between cluster groups and the following selfreported behavioral outcomes: intake of high calcium foods and beverages, days per week of calcium supplement use, days per week of multivitamin use, days per week of vitamin D supplement use, and servings of high calcium foods per day. Statistically significant differences in the means for these variables would indicate that members of each cluster are distinctly different from members of other clusters on the score for that variable or level of the variable they possess.

Table 2

Behavioral Outcome	Measure	Use in Analysis
Calcium Lifestyle	5 Questions; number of servings a day of specific high calcium foods/beverages	Number Servings/Day
Days Reported Taking a Calcium Supplement	1 Question; number of reported days on average per week , taking a calcium supplement	Number of Days = 0-7
Days Reported Taking a Multivitamin	1 Question; number of reported days on average, per week, taking a multivitamin	Number of Days = 0-7
Days Reported Taking a Vitamin D Supplement	1 Question; number of reported days on average, per week taking a vitamin supplement either separately or as part of calcium supplement	Number of Days = 0-7

Variables Tested for Association with Cluster Membership (Specific Aim 2)

CHAPTER 4

RESULTS

Data Management

The CATI staff conducted 604 surveys from June 23, 2010 through March 14,

2011. Participants were excluded from this analysis if he or she had "no answer" on one or more item within a subscale (Figure 2). Participants for whom a proxy answered the survey were excluded from the data analysis. After excluding participants based on these criteria, the total participants numbered 268.

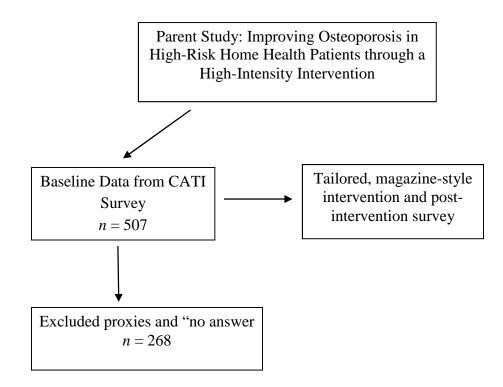


Figure 2. Data collection model.

For descriptive data analysis, outliers and "no answer" responses were coded as "missing." For instance, there were several BMI's that were over 100 where the value entered was likely an entry error.

Demographics

The demographic characteristics of the participants are shown in Table 1. Approximately 89% of the participants were white and 10% were black. Because of the small number of participants from ethnic backgrounds other than white or black (n = 3), those participants were categorized as "other." The mean age was approximately 74 years and the mean years of education was 12.8 years. The data were analyzed using the IBM SPSS Statistics 19 statistical package. Participants were predominantly white (88.6%) and female (83.7%). Because ethnicities other than white and black made up only 1.1% of the study population prior to exclusion, these participants were grouped into the "other" for the rest of the study analyses. Most participants had achieved at least a high school education (mean years of education = 12.4 + 2.6 years).

Table 3

Characteristic	f	Age in	Means	Educ (yrs)	Diagnosis of
	(%)	Years	BMI	(SD)	OP
		(SD)	(SD)		f
					(%)
Female (Total)	223	73.5	27.0	12.3	144
	(83.2)	(9.4)	(6.8)	(3.3)	(65)
White	200	74.5	26.7	12.3	131
	(89.7)	(8.8)	(6.4)	(2.3)	(66)
Black	21	64.7	30.8	12.8	11
	(9.4)	(10.0)	(9.0)	(2.3)	(52)
Other	2	63.5	20.2	15.5	2
	(0.9)	(6.4)	(2.3)	(0.7)	(100)
Male (Total)	45	68.8	26.7	12.5	13
	(16.8)	(10.6)	(7.1)	(3.2)	(29)
White	38	70.2	27.2	12.7	12
	(84.4)	(10.3)	(7.5)	(3.4)	(32)
Black	5	62.4 (8.9)	23.6	12.0	0
	(11.1)		(3.5)	(1.6)	(0)
Other	1	50 (N/A)	27.1	10.0	1
	(2.2)		(N/A)	(N/A)	(100)
Total	268	72.7	12.4	26.9	157
	(100.0)	(9.7)	(2.5)	(6.9)	(59)

Demographic Characteristics of the Population (n = 268)

Note: Table 3 shows the participants' scores on the OPHBM subscales.

Table 4

	Women	Men	Total
Perceived Susceptibility	High: 173 (78)	High: 19 (42)	High: 192 (72)
Category n (%)	Low: 49 (22)	Low: 26 (58)	Low: 75 (28)
Perceived OP Severity mean	20.2 (3.7)	19.0 (4.5)	20.1 (3.8)
(SD)			
Perceived Benefits	15.1 (1.8)	13.8 (2.4)	14.9 (2.0)
Of Supplements on OP			
Prevention			
mean (SD)			
Perceived Benefits of	12.1 (2.8)	13.8 (2.4)	12.1 (2.8)
Supplements for Reducing			
OP Risk			
mean (SD) Perceived Benefits of	11.0 (1.5)	10.1 (1.9)	10.6 (1.6)
Supplements on Feelings	11.0 (1.3)	10.1 (1.9)	10.0 (1.0)
about OP			
mean (SD)			
Perception of Supplements	7.7 (2.1)	9.1 (2.3)	7.9 (2.3)
as Unnecessary (Barriers)	()	, (L)	()
mean (SD)			
Perceived Self-Efficacy for	59.6 (9.4)	61.9 (8.8)	59.9 (9.3)
Taking OP Medicines mean			
(SD)			

Osteoporosis Health Belief Scores for the Population (n = 268)

Scale Reliability Testing

After data collection, we conducted reliability testing on each of the scales with the study population. The results were acceptable for the *Perceived Osteoporosis Susceptibility* subscale (Cronbach's alpha = .89), the Perceived Severity of Osteoporosis subscale without a reported diagnosis (Cronbach's alpha = .72), the *Perceived Severity of Osteoporosis subscale* with a reported diagnosis (Cronbach's alpha = .74) and the Self-Efficacy for Osteoporosis Medications subscale (Cronbach's alpha = .95). However, the results of the reliability testing for the sample were inadequate for *Perceived Benefits of Calcium Supplement Use* (Cronbach's alpha = .61), *Perceived Barriers to Calcium Supplement Use* (Cronbach's alpha = .46), *Perceived Benefits of Vitamin D Supplement Use* (Cronbach's alpha = .61) and the *Perceived Barriers to Vitamin D Supplement Use* (Cronbach's alpha = .42). No meaningful improvements were found with the other supplement subscales.

Because the Cronbach analyses revealed poor reliability for the nutrient supplement subscales, we conducted a factor analysis on these subscales to determine if combinations of items existed that could construct a reliable subscale using the rotated component matrices. After the factor analyses, we re-calculated the Cronbach's alphas to assess the reliability of the new subscales containing the items the factor analysis indicated produced the greatest internal consistency.

The factor analysis on the *Perceived Benefits of Calcium Supplement Use* produced a Kaiser-Meyer-Olkin (KMO) of 0.67 and an eigenvalue of 2.1 with 37% of the variance explained for the first component which was composed of items 1, 2, 3, and 5. The two items that were deleted were negatively worded which could have caused some confusion for the participants. The subsequent reliability analysis on items 1, 2, 3, and 5 produced a Cronbach's alpha = .67.

The factor analysis on the *Perceived Barriers of Calcium Supplement Use* Subscale produced a KMO of .70 and an eigenvalue of 1.5 for the first component with 22% of the variance explained. The first component consisted of items 2, 3, 5, and 7 and produced a Cronbach's alpha = .54.

For the *Perceived Benefits of Vitamin D Subscale*, the factor analysis produced a KMO of 0.72 and an eigenvalue of 2.2 with 36% of the variance explained for

component one which consisted of items 1, 2, 3 and 5. The subsequent Cronbach's alpha = .73.

Factor analysis on the *Perceived Barriers to Vitamin D Supplement Use* produced a KMO of .59 and an eigenvalue of 1.5 with 25% of the variance explained by component one which included items 2, 3, 5, and 6. The subsequent Crohbach's alpha = .50.

Because the Cronbach's alphas for all but one of the subscales produced by the factor analysis were inadequate, revealing subscales that were not internally consistent, we decided to conduct a second factor analysis on the combined calcium and vitamin D benefits subscales and on the combined calcium and vitamin D barriers subscales.

When we combined the *Perceived Benefits of Calcium Supplement Use* and the *Perceived Benefits of Vitamin D Supplement Use* subscales. The factor analysis produced a KMO of .78 and resulted in three components with eigenvalues of 3.9, 2.1, and 1.0. Only items with a factor loading of .5 or higher were included in the components. When we eliminated items with a factor loading of less than .5, components 1 and 2 consisted of 4 items and component 3 consisted of 3 items. Table 5 shows the items comprising each component notated with the same letter after the item.

Table 5

Items in Osteoporosis Supplements Benefits Subscales

Scale

Calcium Supplements Perceived Benefits Subscale

- 1. Taking calcium supplements prevents problems from osteoporosis.^a
- 2. You have lots to gain from taking calcium supplements to prevent osteoporosis.
- 3. You would not worry as much about osteoporosis if you took calcium supplements.
- 4. Taking calcium supplements does NOT cut down the chances of breaking a bone. ^b
- 5. You feel good enough about yourself when you take calcium supplements to prevent osteoporosis. ^c
- 6. Taking calcium supplements does NOT cut down the chances of getting osteoporosis. ^b

Vitamin D Supplement Perceived Benefits Subscale

- 1. Taking vitamin D supplements prevents problems from osteoporosis.^a
- 2. You have lots to gain from taking vitamin D supplements to prevent osteoporosis.^a
- 3. You would not worry as much about osteoporosis if you took vitamin D supplements.^c
- 4. Taking vitamin D supplements does NOT cut down the chances of breaking a bone.^b
- 5. You feel good enough about yourself when you take vitamin D supplements to prevent osteoporosis.^c
- 6. Taking vitamin D supplements does NOT cut down the chances of getting osteoporosis.^b

Note: Items with the same letter loaded with one another on the factor analysis.

The subscale that included items marked with the superscript "a" was named the

"Perceived Benefits of Supplements for Osteoporosis Prevention." The subsequent

reliability testing resulted in a Cronbach's alpha = .75. The subscale that included items

with the superscript "b" was titled the "Perceived Benefits of Supplements for

Osteoporosis Risk." The subsequent reliability testing resulted in a Cronbach's alpha =

.76. The subscale that included items with the superscript "c" was titled the "Perceived

Benefits of Supplements for Producing Positive Feelings." The subsequent reliability testing resulted in a Cronbach's alpha = .71 when item 3 on the calcium benefits subscale was removed.

When we combined the *Perceived Barriers to Calcium Supplement Use* and the *Perceived Barriers to Vitamin D supplement Use* subscales, the factor analysis produced 5components. However, after excluding items with a factor loading of lower than .5 and components with fewer than three items, two components remained (eigenvalues = 1.8 and 1.3). Items that loaded together are delineated by the same letter superscript in Table 6.

Table 6

Items in Osteoporosis Supplements Barriers Subscale

Scale

Calcium Supplements Perceived Barriers Subscale

1. You believe you get all the calcium you need from what you eat and drink.^a

2. Calcium supplements are hard for you to swallow.

3. Calcium supplements do NOT cost too much.

4. You do not mind taking calcium supplements.^D

5. Calcium supplements do not agree with you.^b

6. Taking calcium supplements requires changing your routine, which is hard to do.^b

7. You do not like taking calcium supplements because you already take too many pills.

Vitamin D Supplements Perceived Barriers Subscale

1. You believe you get all the vitamin D you need from what you eat and drink.^a

2. Vitamin D supplements are hard for you to swallow.

3. Vitamin D supplements do NOT cost too much.

4. You believe you get all of the vitamin D you need from the sun.^a

5. You do not mind taking vitamin D supplements.^b

6. You do not like taking vitamin D supplements because you already take too many pills.

Note: Items with the same letter loaded with one another on the factor analysis.

While two scales emerged from this factor analysis, the component with the highest Cronbach's alpha coefficient--comprised of items with superscript "a"-- had a marginally adequate follow-up Cronbach's alpha for a reliable subscale ($\alpha = 0.65$). While this did not strictly meet the standard of a reliable scale (Cronbach's alpha = 0.70), we decided to use it in the analysis. We named this subscale "Perception of Supplements as Unnecessary." Items with subscript "b" showed a much improved Cronbach's alpha with the removal of vitamin barriers item 5; however, this would have left an inadequate number of items (two items) in the scale.

Cluster Analyses Results and Subsequent Means Testing

We conducted four cluster analyses which are summarized in Table 7.

Cluster Analysis A: Participants with and without a Self-Reported OP Diagnosis and Demographic Variables.

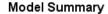
The initial cluster analysis included all of the health belief model subscales as well as the following demographic variables: gender, age, number of years of education, and BMI. Categorical variables were gender and the perceived susceptibility category. We recoded perceived susceptibility into a categorical variable because the researchers on the parent study coded participants who reported having a doctor's diagnosis of osteoporosis as "high susceptibility" and did not administered this subscale to these participants. The logic behind this was to avoid survey fatigue. Continuous variables – including those constructed from the factor analysis - were Perceived Severity of Osteoporosis, Perceived Need for Osteoporosis Nutrition Supplements (a measure of barriers to taking osteoporosis supplements), Perceived Benefits of Supplements for OP Prevention, Perceived Benefits of Supplements for OP Risk Reduction, Perceived

Benefits of Supplements on Feelings about Osteoporosis, Self-Efficacy for Osteoporosis Medications, age, and BMI. The result was a three cluster solution (Figure 3). The cluster quality was fair with a cluster average silhouette (cohesion and separation) of 0.3.

Table 7

Cluster Analysis	п	Demographic Variables	Categorical Health Belief Subscales	Continuous Health Belief Subscales
-				
A: All participants	268	Gender	Perceived	Perceived Severity
		Age	Susceptibility	Perceived Benefits (3)
		Education (yrs) BMI	Category	Perceived Barriers (1)
B: Participants without	107	Gender		Perceived Susceptibility
diagnosis	107	Age		Perceived Severity
		Education (yrs)		Perceived Benefits (3)
		BMI		Perceived Barriers (1)
C: All participants	268		Perceived	Perceived Severity
			Susceptibility	Perceived Benefits (3)
			Category	Perceived Barriers (1)
D: Participants without	107			Perceived Susceptibility
diagnosis				Perceived Severity
				Perceived Benefits (3)
				Perceived Barriers (1)

Components of Individual Cluster Analyses



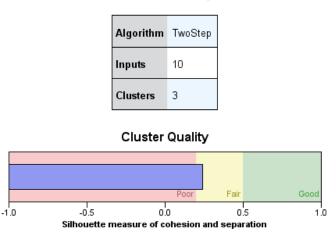


Figure 3. Model summary for Cluster Analysis A.

The variables associated with group membership are presented in Figure 4. The most important predictor of cluster membership was gender with 100% of the member clusters 1 and 2 female and 100% and of the members of cluster 3 males (see Table 6). The predictor importance output ranks the variable on a scale of .00 (least important) up to a 1.00 (most important). The second most important predictor of cluster membership was perceived susceptibility. In this analysis, perceived susceptibility was a categorical variable including participants with a reported diagnosis of osteoporosis categorized as 'high susceptibility.' However, 32% of the participants in the study without a doctor's diagnosis scored in the high susceptibility range on the subscale. So some members of cluster 1 without a diagnosis of osteoporosis perceived themselves as being at high risk for the disease.

Clusters

Input (Predictor) Importance

Cluster	1	2	3
Label	Women with High		J Men with Low
	Perceived Susc	Perceived Susc	Perceived Susc
Dæscription	Members of this group were all ternale; and vere in the category of high perceived susceptibility This is the largest group in this cluster analysis.	Members of this group were al female and were in the category of high perceived susceptibility This group is much smaller than group '.	Members of this group were all mae with over halt in the low perceived susceptibility category. This is the smallest group.
Size	64.8%	18.8%	18.5%
	(169)	(49)	(43)
Inputs			
	Suse Cat	SuscCat	SusoCat
	High Suse (100 0 %)	Louisuse (98.0%)	LouSuso (55.8%)
	.Age	. Age	Age
	72.23	77.96	68.47
	SuppBenPrev	SuppBenªrev	Supp Ben Prev
	10.19	14.86	13.24
	Supp Ben Erro	Suop Ben Erno	Supp Ben Erno
	I 1.01	10.92	10.14
	3EV3UM	3EV3LM	SEVSUM
	20.53	19.45	19.26
	SelfEfficacySum	Sel1Efficacy Surr	Self Efficacy Sum
	59.72	59.49	61.79
	Supp Ben Risk	Suop Ben Risk	Supp BenRisk
	12.01	12.53	12.12
	6d_Yrs	Ed_Yes	Ed_Yrs
	12.40	12.08	12.83
	BMI_Category	BMI_Category	BMI_Category
	2.86	2.82	2.84

Figure 4. Cluster Analysis A cluster characteristics.

Gender had a predictor importance score of 1.00 and susceptibility had a score of 0.79. The third most important variable was age, a weak predictor at 0.09. The largest cluster (n = 169) was composed of all females all of whom were categorized as high susceptibility. The second largest cluster (n = 49) was composed of all females most of whom were categorized as low susceptibility (98.0%). The smallest group (n = 43) was all male of whom 55.8% were categorized as low susceptibility. The summary statistics for each cluster are presented in Table 8.

A one-way analysis of variance (ANOVA) was used to test if cluster membership in analysis 1 was associated with the following OP preventive behaviors: taking a multivitamin (days/week), taking a calcium supplement (days/week), taking a vitamin D supplement (days/week) and the reported number of servings of high calcium foods/beverages a day (dietary calcium; Table 9). Statistically significant differences between clusters were found for both taking a calcium supplement (p = .003) and taking a vitamin D supplement (p = .001). The members of cluster 1 (High Susceptibility Women) reported taking calcium supplements a greater number of days per week than the members of cluster 3 (Low Susceptibility Men; 4.9 days \pm 3.1 vs. 2.98 days \pm 3.3; p =.002). Cluster 1 members also reported taking vitamin D supplements a greater number of days than members in cluster 2 (5.4 days \pm 2.9 vs. 3.5 days \pm 3.5; p = .001). Cluster 3 members (Low Susceptibility Women) also reported taking vitamin D supplements a greater number of days than cluster 2 members (5.5 days \pm 2.7 vs. 3.5 days \pm 3.5; p =.005). No significant differences were found for intake of dietary calcium or taking a multivitamin.

Table 8

Subscale	Cluster Membership (<i>n</i>)	f	M (SD)
Perceived Susceptibility of	1: HS Women (169)	High:100%	
Osteoporosis (Category)	2: LS Women (46)	Low: 0% High: 2.1% Low: 97.9%	
	3: LS Men (43)	High: 42.2% Low: 56.8%	
Perceived Benefits of Supplements	1: HS Women (169)		15.2 ^a (1.8)
for Osteoporosis Prevention	2: LS Women (46)		15.0 ^a (1.6)
	3: LS Men (43)		13.8 ^b (2.4)
Perception that Supplements are	1: HS Women (169)		7.5 ^a (2.1)
Unnecessary	2: LS Women (46)		8.4 ^b (2.3)
	3: LS Men (43)		8.9 ^{b, c} (2.3)
Perceived Benefits of Supplements	1: HS Women (169)		11.0 ^a (1.5)
on Feelings about Osteoporosis	2: LS Women (46)		11.0 ^a (1.3)
	3: LS Men (43)		10.0 ^b (2.0)
Perceived Severity of Osteoporosis	1: HS Women (169)		20.5 ^a (3.6)
	2: LS Women (46)		19.6 ^a (3.5)
	3: LS Men (43)		19.1 ^a (4.6)
Perceived Benefits of Supplement	1: HS Women (169)		12.0 ^a (2.9)
on Osteoporosis Risk	2: LS Women (46)		12.5 ^a (2.6)
	3: LS Men (43)		12.2 ^a (2.8)
Perceived Self-Efficacy for	1: HS Women (169)		59.7 ^a (9.1)
Osteoporosis Medication Adherence	2: LS Women (46)		60.7 ^a (11.3)
	3. LS Men (43)		60.0 ^a (9.3)

Summary Statistics for Health Belief Subscale Scores for Cluster Analysis A

Note: Means with different superscript letters are statistically significantly different.

Note: HS = High Susceptibility; LS = Low Susceptibility

Table 9

	Cluster 1	Cluster 2	Cluster 3	р
	High	Low	Low	
	Susceptibility	Susceptibility	Susceptibility	
	Women	Women	Men	
Calcium Supplements	4.9 ^a	4.5 ^{a,c}	3.0°	.003
(days/week) (SD)	(3.1)	(3.2)	(3.4)	
Multivitamin	4.2	4.9	4.9	.264
(days/week) (SD)	(3.4)	(3.2)	(3.5)	
Vitamin D Supplements	5.4 ^a	5.5 ^a	3.5 ^b	.001
(days/week) (SD)	(2.9)	(2.7)	(3.5)	
High Calcium Foods	2.35	2.1	2.1	.654
(Servings/day) (SD)	(1.5)	(1.5)	(1.6)	

Mean Intake of Supplements and High	Calcium Foods in Cluster Analysis A
-------------------------------------	-------------------------------------

Note: Means with different superscript letter had means that were statistically significantly different.

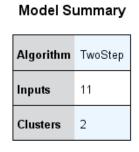
Cluster Analysis B: Participants Without a Self-Reported OP Diagnosis and Demographic Variables

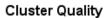
In cluster analysis B, we excluded participants with a diagnosis of osteoporosis since most of the participants with high susceptibility (82%) were thus categorized based on a self-reported doctor's diagnosis, not because of a high score on the susceptibility subscale. The result was two clusters with a fair quality (.2 silhouette for separation and cohesion) where gender was the strongest predictor of group membership (Figures 5 and 6). *Perceived Benefits of Supplements for Osteoporosis Prevention* and *Perceived Benefits of Supplements for Osteoporosis* followed gender as the most important predictors of cluster membership but they were relatively weak predictors. Because gender was the strongest predictor we named Cluster 1 "Women" and Cluster 2 "Men".

The differences between the two groups for subscale scores are shown in Table 10. Women scored higher than men on the *Perceived Benefits of Supplements for* Osteoporosis Prevention, Perceived Benefits of Supplements on Feelings about

Osteoporosis and Perceived Susceptibility subscales while men scored higher than

women on the Perception that Supplements are Unnecessary subscale. Women and men





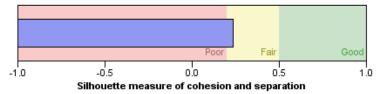


Figure 5. Model summary for Cluster Analysis B.

Clusters

Input (Predictor) Impotance

Cluster	1	2
Label	Women Higher Supp Benefits	-
Vescription	Women: higher perceived benefits of taking OP supplements, lower percoption that they	Men: Jower perceived benefits of taking CP supplements higher perecotion that they dc not need supplements, & Jower perceived suseptibility
šiz:	71.0% (78)	29.0% (31)
in peta		
	\$uppBerPiev 14.89	Sup Een Pre∙ 13.48
	SuppBenEno 11.04	Supp Ben Ernc 0 07
	SuppBarNoNeed 8.08	Supp Ba-NoNeed 9 42
	SuscSum 12.26	SuscSum 10.29
	SEVEUM 20.03	\$EVSUM 18.90
	Age 74 63	Age 71.28
	SuppBenRisk 12.28	Supp Ben Risk 11.71
	6d_7rs 12721	Ed_Yrs 127/1
	Self Pfficacy Sum 60.71	SelfEfficacy Sum 60.10
	EMI_Category 2.89	DML_Category 2 87

Figure 6. Cluster Analysis B cluster characteristics.

Table 10

Subscale	Cluster Membership (n)	Sum Mean ±SD	P Value
Perceived Benefits of	1: Women (76)	14.9±1.7	.004
Supplements for Osteoporosis Prevention	2: Men (31)	13.5±2.3	
Perceived Benefits of	1: Women (76)	$11.04{\pm}1.4$.006
Supplements on Feelings about Osteoporosis	2: Men (31)	9.9±1.8	
Perception that	1: Women (76)	8.1±2.1	.004.
Supplements are Unnecessary	2: Men (31)	9.4±2.1	
Perceived Susceptibility of	1: Women (76)	12.3±3.1	.004
Osteoporosis	2: Men (31)	10.3±3.2	
Perceived Severity of	1: Women (76)	20.0±3.3	.135
Osteoporosis	2: Men (31)	18.9±3.9	
Perceived Benefits of	1: Women (76)	12.3±2.7	.340
Supplements on Osteoporosis Risk	2: Men (31)	11.7±2.7	
Perceived Self-Efficacy for Osteoporosis Medication	1: Women (76)	60.7±9.1	.782
Adherence	2: Men (31)		
	. ,	60.1±13.1	

Summary Statistics for Health Belief Subscale Scores for Cluster Analysis B

 $\alpha = .05$

did not score significantly different on any of the other Health Belief Model subscales.

We conducted an independent *t*-test to determine if cluster membership was associated with osteoporosis preventive behaviors (Table 11). Cluster membership was associated with taking calcium supplements more days per week with cluster 1 (Women) reporting more days than cluster 2 (4.0 days \pm 3.2 vs. 2.2 days \pm 3.2; p =.013) and with taking vitamin D supplements more days per week (5.2 days \pm 2.9 vs. 3.0 days \pm 3.5; *p* =.004). There were no significant differences for reported days per week taking multivitamins (4.4 days \pm 3.3 days vs. 3.73 days \pm 3.5; p = .38) or for reported daily dietary calcium intake (2.0 servings/day \pm 1.4 vs. 2.1 servings a day \pm 1.7; p = .74).

Table 11

	Cluster 1 Women	Cluster 2 Men	р
Calcium Supplements	4.0	2.2	.013
(days/week) (SD)	(3.3)	(3.2)	
Multivitamin	4.4	3.7	.380
(days/week) (SD)	(3.4)	(3.6)	
Vitamin D Supplements	5.2	3.0	.004
(days/week) (SD)	(3.0)	(3.5)	
High Calcium Foods	2.0	2.1	.746
(Servings/day) (SD)	(1.4)	(1.7)	

Mean Intake of Supplements and High Calcium Foods in Cluster Analysis B

Cluster Analysis C: Participants with and without a Self-Reported OP Diagnosis Excluding Demographic Variables

For cluster analyses C and D we excluded the demographic variables so that we could examine the utility of the Health Belief Model subscales alone as clustering variables. In cluster analysis C, we included participants with a diagnosis of osteoporosis; therefore, perceived susceptibility was included as a categorical variable. The result was a model of fair quality with a .4 silhouette for separation and cohesion (Figure 7).

Model Summary



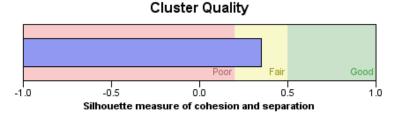


Figure 7. Model summary for Cluster Analysis C.

The most important predictor of cluster membership was *Perceived Susceptibility* to Osteoporosis with all other variables weak predictors (Figure 8). We named cluster 1 "High Susceptibility" and cluster 2 "Low Susceptibility." Differences on the other subscales are summarized in Table 12. Members of the "Low Susceptibility" cluster scored higher on the *Perception that Supplements are Not Necessary* subscale when compared to members in the "High Susceptibility." Members in the "High Susceptibility" group scored higher on *Perceived Severity of Osteoporosis*, *Perceived Benefits of Supplements on Feelings about Osteoporosis*, and *Perceived Severity of Osteoporosis*.

Clusters

Input (Predictor) Importance

01		
Cluster	1	2
Label	High Perceived Susceptibility	Low Perceived Susceptibiliy
Description	Dl-:-+-:	DI-:
	had high perceived susceptbility	People in this cluster had low perceived susceptibility (categorical variable).
Size	72.0% (193)	28.0% (75)
in pu t s		
	SuppBarNoNeed 7.54	Supp BarNo Need 8.93
	SuppBenPrev 15.13	Supp Ben Prev 14.19
	SEVSUM 20.36	SEVSUM 19.01
	SuppBenEmo 10.98	Supp Ben Erno 10.51
	Self Efficacy Sum 59.84	SelfEfficacy Sum 60.33
	SuppBenRisk 12.10	Supp Ben Risk 12.11

Figure 8. Cluster analysis C cluster characteristics.

Table 12

Subscale	Cluster Mombarship (a)	f	Sum Mean ±SD	р
	Membership (n)		$\pm 3D$	
Perceived Susceptibility of Osteoporosis (Category)	1: HS (193)	High: 100% Low: 0%		.000
	2: LS (75)	High: 0% Low: 100%		
Perception that Supplements	1: HS (193)		7.5±2.1	.000
are Unnecessary	2: LS (75)		8.9±2.3	
Perceived Benefits of	1: HS (193)		15.1±1.8	.001
Supplements for Osteoporosis Prevention	2: LS (75)		14.2±2.1	
Perceived Severity of	1: HS (193)		20.4±3.9	.01
Osteoporosis	2: LS (75)		19.0±3.6	
Perceived Benefits of	1: HS (193)		10.9±1.6	.03
Supplements on Feelings about Osteoporosis	2: LS (75)		10.5±1.6	
Perceived Self-Efficacy for	1: HS (193)		59.8 ± 8.9	.72
Osteoporosis Medication Adherence	2: LS (75)		60.3±10.3	
Perceived Benefits of	1: HS (193)		12.1±2.9	.98
Supplement on Osteoporosis Risk	2: LS (75)		12.1±2.6	

Summary Statistics for Health Belief Subscale Scores for Cluster Analysis C

Note: HS = High Susceptibility; LS = Low Susceptibility; $\alpha = .05$

The follow-up *t*-test (Table 13) showed that cluster membership was associated with taking calcium and vitamin D supplements. Cluster 1 (High Susceptibility) reported more days per week for taking calcium supplements than cluster 2 (4.8 days \pm 3.2 vs. 3.6 days \pm 3.3; *p* = .007) and for taking vitamin D supplements more days per week (5.4 days \pm 2.9 vs. 4.4 days \pm 3.2; *p* = .004). There were no significant differences for reported days per week taking multivitamins (4.4 days \pm 3.3 days vs. 3.73 days \pm 3.5; *p* = .38) or for reported daily dietary calcium intake (2.0 servings/day \pm 1.4 vs. 2.1 servings a day \pm 1.7; *p* = .74).

Table 13

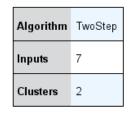
	Cluster 1 High Perceived Susceptibility	Cluster 2 Low Perceived Susceptibility	Р
Calcium Supplements	4.8	3.6	.007
(days/week) (SD)	(3.7)	(3.4)	
Multivitamin	4.2	3.4	.956
(days/week) (SD)	(4.2)	(3.4)	
Vitamin D Supplements	5.4	2.9	.036
(days/week) (SD)	(4.4)	(3.3)	
High Calcium Foods	2.3	1.5	.243
(Servings/day) (SD)	(2.0)	(1.4)	

Mean Intake of Supplements and High Calcium Foods in Cluster Analysis C

Cluster Analysis D: Participants without a Self-Reported OP Diagnosis and Excluding Demographic Variables

For the last cluster analysis, we excluded participants with a diagnosis of osteoporosis and used the continuous susceptibility measure. The result was a cluster of fair quality (.3 silhouette for cohesion and separation; Figure 9). The two most important predictors of cluster membership were *Perceived Benefits of Supplements on Feelings about Osteoporosis* and *Perceived Benefits of Supplements for Preventing Osteoporosis* (Figure 10). We named cluster 1 "Neutral Perceived Benefits of Taking Supplements for Osteoporosis" and cluster 2 the "High Perceived Benefits of Taking Supplements for Osteoporosis." Members in cluster 2 ("High Benefits") scored higher on Perceived Benefits of Supplements on Feelings about Osteoporosis, Perceived Benefits of Supplements for Preventing OP, Perceived Severity, Perceived Susceptibility for Osteoporosis, and Perceived Benefits of Supplements on OP Risk (Table 14).

Model Summary





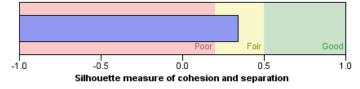


Figure 9. Model summary for Cluster Analysis D.

Clusters

Input (Predictor) Importance

Cluster	2	1
Label	- High Perceived Benefits	Neutral Perceived Benefits
Description	People in this group scored high on perceived Benefits or Supplements for producing positive feelings and for preventing problems from OP.	People in this group were neutral on perceived Benefits or Supplements for producing positive feelings.
Size	60.0% (68)	
in purts		
	Supp Ben Prev 16.68	Supp Ben Prev 12.69
	SEVSUM 20.58	SEVSUM 18.05
	SuseSum 12.32	SuscSum 10.57
	Supp Ben Risk 12.64	Supp Ben Risk 11.20
	Supp BarNo Need 8.20	Supp BarNoNeed 9.02
	Self Efficacy Sum 60.61	Self Efficacy Sum 60.59

Figure 10. Cluster Analysis D cluster characteristics.

Table 14

Subscale	Cluster Membership (n)	Sum Mean ±SD	р
Perceived Benefits of	1: Low Perceived Benefits (44)	9.2±1.4	.000
Supplements on Feelings about Osteoporosis	2: High Perceived Benefits (66)	11.7±0.5	
Perceived Benefits of	1: Low Perceived Benefits (44)	12.6±1.9	.000
Supplements for Osteoporosis Prevention	2: High Perceived Benefits (66)	15.7±0.8	
Perceived Severity of	1: Low Perceived Benefits (44)	18.1±3.8	.000
Osteoporosis	2: High Perceived Benefits (66)	20.6±3.0	
Perceived Susceptibility of	1: Low Perceived Benefits (44)	10.6 ± 3.2	.005
Osteoporosis	2: High Perceived Benefits (66)	12.3±31	
Perceived Benefits of	1: Low Perceived Benefits (44)	11.3±2.1	.003
Supplements on Osteoporosis Risk	2: High Perceived Benefits (66)	12.6±2.9	
Perception that Supplements	1: Low Perceived Benefits (44)	9.0±2.0	.06
are Unnecessary	2: High Perceived Benefits (66)	8.2±2.3	
Perceived Self-Efficacy for	1: Low Perceived Benefits (44)	60.6±13.5	.99
Osteoporosis Medication Adherence	2: High Perceived Benefits (66)	60.6±7.5	

Summary Statistics for Health Belief Subscale Scores for Cluster Analysis D

Note: $\alpha = .05$

The *t*-test analysis (Table 15) showed that cluster membership was associated with calcium intake, multivitamin intake, and vitamin D intake. Members of cluster 2 (High Perceived Supplement Benefits) took calcium more days per week than the members of cluster 2 (Neutral Perceived Supplements Benefits; 4.4 days \pm 3.2 vs. 2.1 days \pm 3.1; *p* = .000). Cluster 2 members also reported taking a multivitamin a greater number of days per week (4.8 days \pm 3.3 vs. 3.2 days \pm 3.5; *p*=.016) and taking a vitamin D supplement a greater number of days (5.3 days \pm 3.0 vs. 3.5 days \pm 3.5; *p*=.006).

Table 15

	Cluster 1 Neutral Perceived Benefits	Cluster 2 High Perceived Benefits	р
Calcium Supplements	2.1	4.4	.000
(days/week) (SD)	(3.1)	(3.2)	
Multivitamin	3.1	4.8	.016
(days/week) (SD)	(3.5)	(3.3)	
Vitamin D Supplements	3.4	5.2	.006
(days/week) (SD)	(3.5)	(3.0)	
High Calcium Foods	1.8	2.2	.107
(Servings/day) (SD)	(1.3)	(1.5)	

Mean Intake of Supplements and High Calcium Foods in Cluster Analysis D

When we evaluated the gender of each of these clusters, we found that cluster 1

was 43% male (n = 19) and cluster 2 was 19% male (n = 13).

CHAPTER 5

DISCUSSION AND CONCLUSIONS

This study was designed to explore the beliefs of a group of home health patients with a high risk of osteoporosis based on a diagnosis of osteoporosis or having sustained a fragility fracture and to determine if those beliefs were associated with the behavioral outcomes of taking dietary supplements for osteoporosis. Because calcium and vitamin D intake are important components of treating osteoporosis and preventing fragility fractures, initiating and maintaining these behaviors among those at high risk is paramount. Few people are able to get adequate levels of these nutrients, so taking calcium and vitamin D supplements is necessary for most patients to achieve adequate levels for fracture risk reduction. Identifying segments of people who are at high risk for osteoporosis and for fragility fractures who have common characteristics can help clinicians provide more effective, individualized interventions designed to adopt and maintain bone protective behaviors such as taking calcium and vitamin D supplements. These methods can also help researchers develop tailored community education materials for high risk people who may not recognize that they are at risk and to increase their likelihood of taking bone protective supplements.

We used cluster analysis as a method of categorizing participants because this method empirically classifies entities (in this case, people) based on their common characteristics (in this case, demographic characteristics and health beliefs) while

creating groups that are as distinctly different from one another as possible (Punj & Stewart, 1984). Punj and Stewart (1984) refer to this as "external isolation and internal cohesion." This analysis method allowed us not only to categorize people but also evaluate a theoretical model – the Health Belief Model – as a whole within clusters rather than as separate constructs within a model and its utility to reveal associations between the group membership and particular health behaviors.

Cluster Analyses

We conducted several cluster analyses to address the first research question of the study, which was to determine if participants in an osteoporosis education intervention study could be segmented into subgroups of similar individuals based on responses to the Osteoporosis Health Belief Model. We included self-efficacy – the belief that one can successfully perform a specific behavior – because many studies do not include this measure and it may be an important determinant of a behavior. The cluster analyses results showed that the health belief model was not a strong determinant of group membership for this population when gender and osteoporosis diagnosis were included in the analyses.

The first cluster analysis included demographic variables (gender, age, education level and BMI) as well as the subscales of the health belief model and the self-efficacy measure. We included participants with a diagnosis of osteoporosis and therefore perceived susceptibility was a categorical variable in this analysis. It is important to note that 82% of the people categorized as "high susceptibility" reported being diagnosed with osteoporosis, therefore, we could more accurately describe this category as "people reporting a doctor's diagnosis of osteoporosis." It is also important to note that of the

people reporting a diagnosis of osteoporosis, 92% were women. Therefore, any time we included people with a diagnosis of osteoporosis, the high susceptibility category was largely composed of women who knew they had osteoporosis.

This initial cluster analysis suggests that gender has a strong influence on cluster membership for those at high risk for osteoporosis. The second most influential variable in this initial analysis was susceptibility category. These two variables were very strongly associated with cluster membership while the rest of the variables were only weakly associated with cluster membership. It is possible that the weak association of the scaled variables was due to gender and susceptibility being the most important variables but also that they were categorical variables and that they created the most cohesive and separate due to their categorical nature. Because the nature of cluster analysis allows a person to be a member of only one group, once their gender was determined, none of the other variables played an important role in group membership. Women were much more likely to view themselves as susceptible to osteoporosis than men. This finding is similar to those of Nayak et al. (2010).

The fact that "high susceptibility" was largely defined by a self-report of doctor diagnosis of osteoporosis has several implications. In the health belief model, a diagnosis is generally viewed as a cue to action (Janz et al., 2002). Different researchers view cues to action somewhat differently with some showing cues to actions as modifiers of perceived threat (Janz et al., 2002) and others viewing cues to actions as having a direct effect on the behavior (Abraham & Sheeran, 2005). While our results do not answer the question of how cues to action affect the components of the health belief model, our results do strongly suggest that a self-reported diagnosis of osteoporosis was strongly associated with cluster membership and subsequent intake of calcium and vitamin D

supplements. This suggests that a doctor's diagnosis alone may have a significant effect on patients' supplement-taking behavior and warrants further investigation.

In cluster analysis B, we excluded people with a diagnosis of osteoporosis because the first cluster analysis strongly suggested that people with and without a reported diagnosis are different in their perceptions and behaviors. Again, gender was the most important determinant of group membership. The other factors were only weakly influential on group membership. For analyses C and D, we eliminated the demographic variables in order to examine the utility of the health belief model constructs for group membership when gender is not a factor. Analysis C yielded the highest quality model (.4 cluster silhouette) and included people with and without a diagnosis of osteoporosis. The results showed susceptibility category had the strongest influence on group membership with other variables showing virtually no importance. However, since the susceptibility category may be viewed as a proxy for gender and diagnosis, we examined each cluster for its gender content.

The number of men in cluster A (the "high susceptibility" group) numbered 13 (29%). The number of men in cluster B (the "low susceptibility" group) numbered 26 (35%). So gender, diagnosis, and perceived susceptibility category are all so closely tied together that gender can serve as a proxy for the susceptibility category and vice versa.

When we excluded people with a diagnosis and did not include gender as a predictor variable (analysis D), two of the supplement benefits subscales (Perceived Benefits on Positive Feelings and Perceived Benefits on Preventing Problems from Osteoporosis) emerged as the strongest predictors of cluster membership with the other variables emerging as weak predictors of cluster membership. Cluster 1 (neutral beliefs about supplement benefits) was 43% male (n=19) and cluster 2 (positive beliefs about

supplement benefits) was 20% male (n=13). Again, this supports that factors associated with group membership are different for people who have a diagnosis and for people who do not when beliefs and perceptions are the clustering variables and not gender. It also suggests that for people without a diagnosis of OP, their beliefs about the benefits of supplements may play an important role in their group membership and subsequent behaviors.

When we evaluated the participants who did not report a doctor diagnosis of osteoporosis, we found that most of the participants had neutral scores on perceived susceptibility. The mean score on the susceptibility subscale among people without a self-reported doctor's diagnosis of osteoporosis was 11.62. Similar to the findings of Nayak et al. (2010) this suggests that despite possessing the characteristics of high risk for osteoporosis, people do not recognize that they are at high risk.

Across all of the cluster analyses, the mean differences on several of the health belief model subscales were statistically significant between the clusters, however, the differences may not have been meaningful. For instance, in cluster analysis B, cluster one members (women) had a mean sum of 14.9 on perceived benefits of supplements for OP prevention while men had a mean sum of 13.5. Considering that this subscale was a 3item subscale using a 5-point Likert scale, both of those means fall close to "neutral". While they are statistically significantly different, how meaningful those differences are is questionable and warrants exploration. Other studies have also reported differences between groups on health belief subscale scores but often those differences are small and the whether those differences result in differences in behaviors should be evaluated with longitudinal studies (Tussing & Chapman-Novakofski, 2005).

Associations Between Clusters and Osteoporosis Protective Behaviors

The second study aim was to determine if cluster membership was associated with differences in bone protective behaviors, we compared cluster means (ANOVA and *t*-tests) for taking supplements and intake of dietary calcium for each of the analyses. All of the cluster solutions produced groups that differed significantly on taking calcium and vitamin D supplements but not multivitamins or the number of servings a day of high calcium foods. Cluster solution 4 also produced groups that differed on multivitamin use.

Because of the cross sectional design, we cannot determine if the associations we found with bone protective behaviors are persistent over time or if the behaviors changed over time in relationship to diagnosis or other factors. Among all of the cluster analyses, the groups that reported more frequent use of supplements than other groups were predominantly groups characterized by female gender (analyses A and B), a reported diagnosis of osteoporosis (analyses A and C), or perceiving supplements as beneficial to preventing problems with osteoporosis (analysis D).

Our study showed that gender had the strongest influence on cluster membership and on bone protective behaviors. These findings are consistent with other researchers. Courtney's review of the empirical data (2000) showed that gender is the most consistent socio-demographic predictor of health behavior and that men are much more likely than women to engage in risky behaviors such as alcohol use, tobacco use, and not seeking medical care. These findings are supported by research that shows that men are less likely than women to adopt healthy behaviors and often exhibit different health beliefs than do women. These differences may be deeply rooted in perceptions of masculinity. Traditional male socialization and acceptance of male social norms often encourage men to engage in risky health behaviors (Mahalik, Burns, & Syzdek, 2007).

Men's perceptions of their masculinity may play a significant role in their likelihood of perceiving themselves to be at health risk and to take preventive measures (Courtenay, 2000).

Research specific to osteoporosis also supports that men feel less susceptible to this disease which is often viewed as a "woman's disease." Doheny, Sedlak, Estok, and Zeller found that men scored lower on perceived susceptibility to osteoporosis than did women despite over half of them had been diagnosed with osteopenia or osteoporosis (2007). Men were also more likely to perceive more barriers to and fewer benefits of calcium intake than were women. In a review of gender differences and fracture risk, Geusens and Dinant concluded that, while osteoporosis is underdiagnosed in both women and men, it is more pronounced in male patients (2007). They also concluded that gender differences in perceptions about osteoporosis may contribute to missed diagnoses of osteoporosis in men. Juby and Davis found similar gender gaps in knowledge about osteoporosis, calcium supplementation, and awareness that osteoporosis could affect them (2001). In a cross-sectional study designed to examine the osteoporosis health beliefs of younger and older men and women, Johnson and colleagues found that men and women perceived the seriousness of osteoporosis relatively equally however, the men perceived themselves to be significantly less susceptible than the women surveyed (Johnson, McLeod, Kennedy, & McLeod, 2007).

These findings coupled with the strong influence of gender on cluster membership, suggest that interventions designed specifically for men should be tested in a longitudinal pre-/post-test or a randomized controlled trial. Researchers and clinicians who work with osteoporosis susceptible men must recognize that men present a particular challenge when preventing and treating osteoporosis and that gender-specific

strategies may be necessary with the male population. Interventions and health messages must be tailored and tested based on the findings that the traditional socialization of men may lead them to perceive themselves at less risk for disease and also make them more likely to engage in risky behaviors or in fewer health protective behaviors. The challenge with men will likely be even greater with a disease such as osteoporosis that, while more common in women, is often viewed as a "women's only" disease.

The second strongest influence on cluster membership and also on bone healthy behaviors was a self-report of physician diagnosis of osteoporosis. Again, our findings are consistent with those of other researchers. In a randomized, controlled trial, researchers found that women who were given information about their bone mineral density from their DXA scans were more like to increase calcium compared to women were not given similar information (Estok, Sedlak, Doheny, & Hall, 2007). In a cluster analysis similar to our study, Cline and Worley found that women in their first cluster were more likely to have been tested for osteoporosis and to have been given a diagnosis (2006). Members of this cluster were also more likely to be taking calcium supplements than members of the other clusters. Chang and colleagues found that the experience of having a bone density test positively correlated with women's intention to prevent osteoporosis (Chang, Chen, Chen, & Chung, 2003). Giangregorio and colleagues found patients' beliefs about their risk for osteoporosis and future fracture were strongly influenced by their beliefs about whether they actually have osteoporosis – information that the researchers point out is often influenced by interactions with health care professionals (Giangregorio, et al., 2009). Other studies show that patient-doctor communication can improve adherence. Using semi-structured interviews, patients with glaucoma reported greater adherence to taking their medications when they reported

being educated about their condition by their doctor (Friedman, Hahn, Gelb, Tan, Shah, Kim, et al., 2008). In a meta-analysis of empirical studies that examined physician communication and adherence, Haskard Zolnierek and DiMatteo concluded that there is a 19% higher risk of non-adherence among patients whose physician poorly communicates (2009). They also found that the odds of patience adherence were 1.62 times greater when physicians received communication training compared to physicians who did not receive communication training.

While diagnosis of osteoporosis seems to positively influence at least some osteoprotective behaviors, physicians may have to be educated on identifying at-risk patients and ordering the appropriate test to diagnose the patients. Current research shows that many at-risk patients are not being identified and tested for osteoporosis (McLeod & Johnson, 2011; Gallagher, et al., 2002; Bessette, et al., 2008). Even when patients have sustained a fragility fracture, diagnosis or treatment may be as low as 24% with decreasing rate of treatment with increasing age of the patient (Freedman, Kaplan, Bilker, Strom, and Lowe, 2000). The lack of diagnosis is a problem for both genders but may be more pronounced in men. In a retrospective chart review, researchers found that the diagnosis of osteoporosis was documented in 14% of low trauma hip fracture patients at discharge and in 26% of the patients at follow up (Follin, Black, & McDermott, 2003). They also found that men were less likely than women to be diagnosed and treated for osteoporosis.

Self-Efficacy

Our study results did not support the role of self-efficacy as influencing cluster membership and the resulting associations with bone protective behaviors. Scores on the self-efficacy subscale were consistently high across this population and no differences

were detected between cluster groups in any of the analyses which may explain its lack of influence. However, self-efficacy should not be dismissed as a potentially important factor in other populations with different characteristics.

The cluster analyses results as a whole suggest that people with and without a self-reported doctor diagnosis of osteoporosis cluster may view the behaviors of taking bone protective supplements differently and that a clinician's clear communication of an OP diagnosis may be a strong motivator for behavior change. However, longitudinal designs are necessary to investigate this question. The results of our cluster analysis suggests that there may be important differences between the home health/home bound population when compared to other people at high risk for osteoporosis but who are not home bound.

Most cluster analyses do not include gender and other demographic characteristics as clustering variable but rather evaluate the clusters afterward for their demographic content. Our results show that gender may be an important clustering variable. Our results were similar to those of Cline and Worley (2006) who found that perceived susceptibility and a diagnosis of osteoporosis were strongly associated with cluster membership. However, they did not include demographics (their study population was all female) nor physician diagnosis in their cluster analysis as clustering variables. They evaluated their clusters on the frequency of physician diagnosis. When considering the use of cluster analysis in a practical way – such as a clinical or public health intervention – it may be useful to use easy-to-determine variables such as gender, age, diagnosis, as part of the clustering variables. It is not always feasible to gather data on individual's health beliefs. Determining if groups exist that are similar in their beliefs based on more

easily identified characteristics may help researchers develop education materials that are relevant and usable in clinical and public health settings.

Subscale Development

We developed four new osteoporosis health belief subscales because previous subscales were designed to examine beliefs about dietary calcium intake – not supplemental calcium intake. Also, there were no subscales in existence that examined beliefs about taking vitamin D supplements. We developed and tested these scales on people in the same age group as those in the study's sample population. The subscales developed had Cronbach's alphas of greater than .70 indicating that the subscales were internally consistent. The four subscales also had strong Pearson correlation coefficients for test/re-test reliability.

However, when we computed Cronbach's alpha coefficients for these same subscales with the study population, we did not get the same results. This finding could have been due to fundamental differences between the population we tested the subscale on and the study population, even though the testing population was drawn from patients who were also considered to be at high risk for osteoporosis. Because the study population is receiving home health care, the participants could have more co-morbidities and be in generally poorer health. What is clear is that this finding underscores the importance of careful development and application of subscales and the importance of conducting reliability testing on subscales after data collection within the study population.

These results necessitated the subsequent factor analysis to form new subscales that we could use for our study population. When we combined the calcium and vitamin D supplement benefits items, we were able to produced subscales with greater internal consistently. This suggests that perceptions of and beliefs about both calcium and vitamin D supplementation are similar for both nutrients and that evaluating these perceptions and beliefs separately is unnecessary. Interestingly, one of the subscales that emerged focused on how taking supplements affected people's feelings about having osteoporosis. When we combined the barriers to taking calcium supplements and the barriers to taking vitamin D supplements, only one subscale emerged. We named this subscale "The Perception of Supplements as Unnecessary". High scores on this subscale indicate that a person feels that he or she is getting enough calcium and vitamin D from sources other than supplements. This measure could have utility in clinical practice and in intervention development to identify people who mistakenly believe that they are getting enough calcium from foods and that even limited sun exposure will maintain adequate levels of vitamin D. Items that addressed supplement cost, difficulty with swallowing pills, and general inconvenience did not produce a reliable subscale. These may still be issues that prevent individuals from taking supplements however.

The results of our subscale findings support the beliefs of some researchers that the HBM subscales are often not unidimensional. This concept is described by Abraham and Sheeran (2005) and our findings support the multidimensionality of the HBM subscales in our population. When we evaluated the supplement subscales as overall supplement barriers and benefits (as opposed to separating them into calcium and vitamin D supplement benefits and barriers) reliability was increased. The only barriers items that formed a reliable scale were in actuality a perception that supplements were not needed because of the belief that the participant was getting enough from natural sources. The barriers that are typical in the HBM – cost, inconvenience, difficultly in taking the pills –

did not hold up as subscales in our analyses. Because our study population seemed to cluster based on self-reported diagnosis, it is possible that the subscales would have maintained their reliability within one of these subpopulations.

Our finding that the subscales for calcium and vitamin D supplements were not reliable in our study population also show that subscales that are reliable within one population may not prove reliable within another. The population we used to test the subscales prior to use in the study population was a convenience sample of people who had been referred to the UAB Osteoporosis Prevention and Treatment Clinic and had agreed to participate in research. While this population was similar to our study population in their risk for osteoporosis and age, it is likely that they differed from our study population in key ways. First of all, the study population was a home health population and therefore likely to have an increased number of comorbidities (Kirby & Lau, 2008; National Home Health and Hospice Care Survey, 2000). There also may have been differences between the populations for key demographic characteristics such as SES and diagnosis of OP.

Other Findings

Our results showed that in this population, taking nutrient supplements was highly bimodal in frequency distribution. We asked participants how many days a week he or she took a calcium supplement, a multivitamin, or a vitamin D supplement (separately or as part of their calcium supplement). The data showed that most people answered either "0" or "7" with very few responses falling between 0 and 7. From a data management perspective, this finding suggests that in future studies, taking supplements should be categorized as "low" or "high" to avoid large standard deviations in the statistical

reporting. From a behavioral perspective, this finding suggests that taking supplements may be a fairly "all or nothing" behavior.

Study Limitations

This study had several limitations. The study was a cross sectional study in design so the results are limited to the temporal context of a single point in time. The findings do not allow us to draw conclusions on the long-term maintenance of the behaviors of interest. Also, the nature of self-report data on nutritional intake is subject to self-report bias. However, studies conducted on the reliability of food frequency questionnaires show that data on macronutrient intake such as total calories is much more likely to be over-reported than micronutrient intake or intake of specific food groups.

A second limitation of the study was that the susceptibility subscale was not administered to all of the participants. The researchers over the parent study wanted to limit the number of questions and so, if a patient reported that a doctor had told them that they had osteoporosis, they felt it was unnecessary to administer the perceived susceptibility to OP subscale. Therefore, to include all of the participants, we coded perceived susceptibility two ways: using the original continuous sum, and as a categorical variable. It is possible that a diagnosis of osteoporosis is not the same as a high perceived susceptibility for the disease. Therefore, some of the participants who were coded as high susceptibility due to a doctor's diagnosis, may not view themselves as susceptible. Also, within the category of people with high susceptibility, 82% (n = 157) reported having a diagnosis. Therefore, the majority of the participants categorized as "high perceived susceptibility" were categorized as such due to a self-report of doctor's diagnosis, not due to scoring high on that subscale. Another limitation of the study was the loss of many subjects due to "no answer" responses on the survey. We could not code "no answer" as "neutral" because neutral means not feeling one way or the other while "no answer" indicates not knowing how one feels or simply a desire not to respond. Because of the nature of the analysis, a "no answer" on just one item meant that the participant had to be excluded from the analysis since the model as a whole formed the basis of the research.

The lack of a strong barriers subscale may have underestimated the role that perceived barriers to taking supplements in the cluster formation and in the associated OP preventive behaviors. The scale resulting from the factor analysis had a Cronbach's alpha of .65. We normally would only accept a Cronbach's alpha \geq .70; however, this was our only measure of barriers to supplement use.

Also, the subscale measured people's belief that they are getting enough calcium and vitamin D through foods and the sun and not other barriers such as difficulty swallowing pills or the cost. This may have limited our ability to accurately assess other barriers to using nutrient supplements. However, none of the questionnaire items that addressed these issues correlated with one another so a usable subscale that addressed other types of barriers did not emerge.

The fair cluster quality for all for all of the cluster analyses was also a limitation to making strong conclusions. The cluster silhouette score is calculated using each cluster member's distance from the average of the group (dissimilarity from its own cluster) and then comparing this distance to the average distance to the other groups. A good cluster quality of .5 or above is desirable, indicating that the clusters formed have a reasonable level of internal cohesion and are distinctly separate from one another.

Implications for Future Research

Most public health studies using cluster analysis, including this one, have used cluster analysis to group people into meaningful clusters and show associations between group membership and particular health behaviors. However, the real value of cluster analysis is in its potential to help us create more effective public health interventions in terms of both cost and effectiveness. Public health researchers are increasingly turning to the fields of advertising and marketing as models for improving message construction and behavioral interventions. Cluster analysis has been used for decades by marketers to segment their target audiences and tailor their messages to each segment.

The clusters we found suggest that segments of the population exist that may be more effectively reached through tailored behavioral interventions. Typically, tailoring in health behavior research is done by taking each individual's score on a particular set of constructs and including education pieces that address that particular construct. This "piecemeal" approach may result in too much confusing information for the health consumer. Experts in the area of readability, comprehension, and usability of health information advise researchers and practitioners to limit interventions to 1 to 3 main messages (Neuhauser & Paul, 2011). By using cluster analysis to determine group membership, we may be able to develop more cohesive, simpler, and more finely targeted messages and education materials based on a group profile as opposed to a set of individual scores on individual constructs.

Researchers may need to use very different strategies when developing interventions for people with and without diagnosis and for men and women. Perceived susceptibility seemed to be closely related to diagnosis. People who did not have a diagnosis of OP from a doctor, tended to score very low on the perceived susceptibility

subscale suggesting that a simple doctor's diagnosis for high-risk patients can achieve a more accurate perception on this construct. This finding has implications for interventions at the clinician level. Educating physicians on the importance of giving patients a clear, definitive diagnosis may have an impact on improving the likelihood that high risk patients will take calcium and vitamin D supplements.

The home health care population is particularly vulnerable to osteoporosis and fragility fractures due to often advanced age, poor nutritional status, the presence of comorbidities, and poor medication adherence. Randomized controlled trials that examine strategies to improve adherence to bone health supplements, medications, and nutritional status on the risk of initial and subsequent fragility fracture are necessary to improve patient quality of life, medical outcomes, and also reduce the medical costs of fractures.

Conclusions

Gender and a clear diagnosis of OP from a physician appear to be important factors in determining group membership based on common characteristics among a population of older adults at high risk for osteoporosis. Overall, the health belief model did not play an important role in determining how people were assigned to a group in this two-step cluster analysis. However, when gender and susceptibility category were excluded, two of the benefits subscales were found to be the most important factors in determining cluster membership.

In people without a diagnosis, group membership was largely determined by gender and beliefs about the effects of supplements on feelings about osteoporosis and their beliefs about the role supplements play in preventing problems from osteoporosis.

In people with a diagnosis, none of these factors strongly influenced their group membership.

These results strongly suggest that gender and physician diagnosis are important grouping factors in older adult high risk patients. As long as these two factors came into the analysis, health belief model constructs did not differentiate groups to a large degree. People may appear to have distinctly different beliefs and behaviors based on diagnosis. This supports the view that prevention and disease-state perceptions may strongly influence behaviors. Within all analyses, clusters showed significant differences in use of calcium and vitamin D supplements making these groupings potentially useful for clinical and public health interventions with high-risk older adults. These results have implications for future research to determine if health belief interventions based on cluster membership are effective in initiating and maintaining behavior change.

Finally, these conclusions must be made within the context of our population. While our results are consistent with others regarding gender and physician diagnosis, our population is different than in these studies. Most studies use either the free-living population or people living in nursing homes or in assisted living. The home health population falls between these two populations. People in home health are receiving ongoing care from health care professionals but not for an indefinite period of time. This situation provided us with an opportunity to educate and encourage diagnosis and behavior change but long-term adherence will continue to be a challenge since this care will end at some point. This "in-between" population presents a unique opportunity to provide care and the long-term skills to improve bone health and reduce debilitation fractures in a vulnerable population.

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APPENDIX A

UAB INSTITUTIONAL REVIEW BOARD APPROVAL FORMS



Institutional Review Board for Human Use

Form 4: IRB Approval Form Identification and Certification of Research Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 23, 2012. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines.

Principal Investigator:	KITCHIN, ELIZABETH M
Co-Investigator(s):	
Protocol Number:	X090814007
Protocol Title:	Testing Health Belief Subscales for Calcium and Vitamin Supplements in a High Risk for Osteoporosis Population

The IRB reviewed and approved the above named project on $\frac{g}{r_1/2} \frac{g}{r_2}$. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: <u>8-19-09</u>

Date IRB Approval Issued: 8/15/05

Marilyn Doss, M.A. Vice Chair of the Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building
701 20th Street South
205,934,3789
Fax 205.934.1301
irb@uab.edu

The University of Alabama at Birmingham Mailing Address: AB 470 1530 3RD AVE S BIRMINGHAM AL 35294-0104

Project Revision/Amendment Form

(PLEASE TYPE: In MS Word, highlight the shaded, underlined box and replace with your text; double-click checkboxes to check/uncheck.)

- Federal regulations require IRB approval before implementing proposed changes.
- Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.).

Complete this form and attach the changed research documents

Today's Date: 8/17/10

1. Contact Information

Principal Investigator's Name: Jeffrey R. Curtis, MD, MPH BlazerID; jcurtis E-mail: jcurtis@uab.edu Contact Person's Name: Mary Elkins Melton BlazerID: melkins E-mail: melkins@uab.edu Telephone: 5-2176 Fax: 5-6859 Campus Address: FOT 820

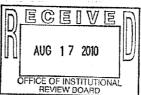
2. Protocol Identification

Protocol Title: Improving Osteoporosis Care in High-Risk Home Health Patients through a High-Intensity Intervention (Eli Lilly and Company)

IRB Protocol Number: X080401004

Current Status of Project (check only one):

- Currently in Progress (Number of participants entered: <u>509</u>)
- Study has not yet begun (No participants entered) Closed to participant enrollment (remains active)-
- Number of participants on therapy/intervention:
- Number of participants in long-term follow-up only: Closed to participant enrollment (data analysis only)-
 - Total number of participants enrolled:



irb

This submission changes the status of this study in the following manner (check all that apply):

- Protocol Revision
- **Revised Consent Form**

Protocol Amendment

Study Closed to participant entry

Addendum (new) consent form

Enrollment temporarily suspended by sponsor 🖾 Change in protocol personnel

Study Closure Other, (specify)

3. Reason for change

Briefly describe, and explain the reason for, the change. If normal, healthy controls are included, describe in detail how this change will affect those participants. Include a copy of the protocol and any other documents affected by this change (e.g., consent form, questionnaire) with all the changes highlighted.

At this time we are adding Elizabeth Kitchin to project personnel.

Role:	CoOR- Other -AND/OR- Consent Process
Full Name:	Elizabeth Kitchin 🗸
Primary UAB Dept.:	Nutrition Sciences
(Employer if not UAB)	
Degree(s) / Job Title:	Asst Prof SHRP
Additional Qualifications	
pertinent to the study:	

Name: Elizabeth Kitchin

Do you or your immediate family have any of the following? (Check all that apply) An ownership interest, stock options, or other equity interest related to the

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research of any value.

Compensation related to the research unless it meets two tests:

- Less than \$10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a
- patent, trademark, copyright, or licensing agreement. Board of executive relationship related to the research, regardless of

compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently on file with the <u>CIRB</u> and the completed CIRB Evaluation has to be available before the IRB will conduct its continuing review.

4. Does this change revise or add a genetic or storage	of samples component?
--	-----------------------

If yes, please see the Guidebook to assist you in revising or preparing your submission, or call the IRB office at 934-3789.

- 5. Does the change affect subject participation (e.g., procedures, risks, costs, location of services, etc.)? ☐Yes ⊠No If yes, Fiscal Approval Process (FAP)-designated units complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP, see www.uab.edu/ohr.
- 6. Does the change affect the consent document(s)?
 If yes, briefly discuss the changes.
 Include the revised consent document with the changes highlighted.
 Will any participants need to be reconsented as a result of the changes?
 If yes, when will participants be reconsented?

Signature of Principal Investigator

PROVED an Vice Chair - IP

□Yes ⊠No

TYes No

10

224 - Alacare Lilly project-revision-amendment 100817.doc 10/15/08



Institutional Review Board for Human Use

Form 4: IRB Approval Form Identification and Certification of Research Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on August 29, 2016. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	KITCHIN, ELIZABETH M
Co-Investigator(s):	
Protocol Number:	E110829002
Protocol Title:	A Cluster Analysis Based on the Health Belief Model of Alacare Patients at High Risk for Osteoporosis

The above project was reviewed on $\underline{92311}$. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CF46.101, paragraph $\underline{++}$.

This project received EXEMPT review.

IRB Approval Date: 9-23-11

Date IRB Approval Issued: 9 23 11

marily las

Marilyn Doss, M.A. Vice Chair of the Institutional Review Board for Human Use (IRB)

Investigators please note:

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building 701 20th Street South 205.934.3789 Fax 205.934.1301 irb@uab.edu

The University of Alabama at Birmingham Mailing Address: AB 470 1530 3RD AVE S BIRMINGHAM AL 35294-0104

APPENDIX B

SURVEY FROM PARENT INTERVENTION STUDY

Osteoporosis Beliefs and Medication Adherence Survey (Second Survey)

Hello! My name is _______. I'm calling on behalf of the University of Alabama at Birmingham.

We spoke a few months ago about a study about home health care and you answered some questions for me about your general health and your use of medications. I am calling today to ask you some additional questions about your health and medications.

Before we continue, there are a couple of things that I need to tell you. The purpose of our program is to improve care for patients that may be at risk for osteoporosis or thinning bones. If you decide to participate, we will ask you questions about your use of medications, about your general health, and your beliefs about osteoporosis.

This call will take about 20 minutes. At the completion of the telephone survey, we will mail you a \$20 VISA gift card.

All information you provide is confidential and you will not be identified by name and no information will be shared with anyone.

Your participation in this interview is voluntary. There will be no penalty if you decide not to do the survey. You are free to withdraw from this survey at any time. Your choice to not participate in this survey will not affect your relationship with Alacare Home Health and Hospice or the University of Alabama at Birmingham in any way.

Do you have any questions? Yes (If yes, respond to their questions) No (If patient indicates not interested) Thank you for your time. Have a good day! (If patient indicates that now is not a good time)

When would it be a good time to call back Day_____, Time_____,

(If interested) Great!

There is no right or wrong answer to any of the questions I will be asking-just answer the best you can. If I ask you any question you would prefer not to answer, just let me know and I'll move on to the next question.

Osteoporosis Beliefs and Medication Adherence Survey (Second Survey)

When we last spoke you were receiving care from Alacare Home Health and Hospice. Are you currently receiving care from Alacare?

a. Yes

b. No

Interviewer: Osteoporosis is a condition in which the bones become excessively thin and weak so that they are fracture prone (break more easily). I am going to ask you a few questions about osteoporosis and your chances of breaking a bone.

1. Has a doctor or other health provider ever told you that you had osteoporosis?

- a. Yes
- b. No

2. In the past 6 months have you broken any of the following bones? (Please check yes for ALL that apply)

- a. Hip
- b. Wrist
- c. Upper arm
- d. Spine/compression fracture
- e. Pelvis
- f. Rib
- g. Other, please specify:____

3. In what month did your most recent broken bone happen?

____Month

4. Perceived Risk of Fractures from Osteoporosis (item analysis)

- How high do you think your chances are of breaking a bone in the next 10 years?
 - a. About 1 in a hundred people like me will have a broken bone.
 - b. About 5 in a hundred people like me will have a broken bone.
 - c. About 10 in a hundred people like me will have a broken bone.
 - d. About 20 in a hundred people like me will have a broken bone.
 - e. About 35 in a hundred people like me will have a broken bone.

If patient stated they were on a medication at baseline, go to question 2. If patient was not on an osteoporosis medication, go to question 4

5. When we last spoke, you said you were taking ______. Are you still taking _____?

a. Yes (If oral BP skip to question 10; All other skips to question 17)

b. No (go to question 3)

6. If no, what were the reasons you stopped taking your osteoporosis medicine (check all that apply)?

INTERVIEWER INSTRUCTIONS: Please begin this question as an open ended question and circle answers that correspond to the participant's responses under the "unprompted, yes". For any choices that the participant does not state, ask the participant if that choice was a reason that applies to him or her. If the answer is "yes", please circle "prompted yes".

(NOTE: After completing this question interviewer will skip to question 25 except item T)

	Unprompted	Prompted
I didn't feel it was helping/working	Yes	Yes
I had side effects from the medicine	Yes	Yes
i. ONJ	Yes	
ii. GI problems	Yes	
iii. Joint pain	Yes	
iv. Allergic reaction	Yes	
v. Infection	Yes	
vi. Other	Yes	
It was difficult to take the medicine as directed	Yes	
The medicine was too expensive/cost concerns	Yes	Yes
I was worried about the long term risks/side effects		
of the medicine	Yes	
My doctor told me to stop taking the medicine	Yes	Yes
I was taking too many other medicines	Yes	
It was difficult for me to get the prescription filled	Yes	
I didn't think I needed to take it any longer	Yes	
I took it as long as I needed to	Yes	
I don't like taking medications	Yes	
I don't like the inconvenience of taking the medication	Yes	
I wanted to use diet and/or exercise instead	Yes	
l wanted to only use calcium and vitamin D	Yes	
I wanted to use other non-prescription treatments		
instead	Yes	
I have a hard time swallowing pills	Yes	
I didn't think my osteoporosis was bad enough for me t	to	
need medication	Yes	
I had a hard time remembering to take it	Yes	
I never wanted to take it to begin with	Yes	
Started a different medication (if yes, go to quest. 9)	Yes	Yes
Other	Yes	
If other,		

7. Since we last spoke, have you started taking a new medication for osteoporosis?

a. Yes (continue to question 9)

b. No (continue to question 5)

8. Have you talked to your doctor or health care provider about starting a medication to lower your risk for breaking a bone?

a. Yes (continue to question 7)

b. No (continue to question 6)

- 9. Are you aware that there are medications for lowering your risk for breaking a bone?
 - a. Yes (continue to question 25)
 - b. No (continue to question 25)
- 10. Did your doctor or health care provider recommend or offer starting you on a medication for lowering your risk for breaking a bone?
 - a. Yes (continue to question 8)
 - b. No (continue to question 25)
- 11. Why didn't you take the medication that was offered/recommended by your doctor?

INTERVIEWER INSTRUCTIONS: Please begin this question as an open ended question and circle answers that correspond to the participant's responses under the "unprompted, yes". For any choices that the participant does not state, ask the participant if that choice was a reason that applies to him or her. If the answer is "yes", please circle "prompted yes".

(NOTE: After completing this question interviewer will skip to question 25)

	Unprompted	Prompted
a. I didn't feel it would help/work	Yes	Yes
b. I was worried about side effects from the medicine	Yes	Yes
i. ONJ	Yes	
ii. GI problems	Yes	
iii. Joint pain	Yes	
iv. Allergic reaction	Yes	
v. Infection	Yes	
vi. Other	Yes	
c. It was difficult to take the medicine as directed	Yes	
d. The medicine was too expensive/cost concerns	Yes	Yes
e. I was worried about the long term risks/side effects		
of the medicine	Yes	Yes
f. I was taking too many other medicines	Yes	
g. It was difficult for me to get the prescription filled	Yes	
h. I didn't think I needed to take it	Yes	
 I don't like taking medications 	Yes	
j. I don't like the inconvenience of taking the medication	Yes	
I wanted to use diet and/or exercise instead	Yes	
. I wanted to only use calcium and vitamin D	Yes	
m. I wanted to use other non-prescription treatments		
instead	Yes	
n. I have a hard time swallowing pills	Yes	
o. I didn't think my osteoporosis was bad enough for me t	to	
need medication	Yes	
p. I would of had a hard time remembering to take it	Yes	
q. I never wanted to take it to begin with	Yes	
r. Other	Yes	
s. If other,		

12. What is the name of the medication?

a.	Fosamax (alendronate)	Yes	No (if yes, go to question 10)
b.	Actonel (risedronate)	Yes	No (if yes, go to question 10)
c.	Boniva (ibandronate) – Oral	Yes	No (if yes, go to question 10)
d.	Boniva (ibandronate) – IV	Yes	No (if yes, go to question 17)
e.	Miacalcin (calcitonin)	Yes	No (if yes, go to question 17)
f.	Evista (raloxifene)	Yes	No (if yes, go to question 17)
g.	Forteo (teriparatide)	Yes	No (if yes, go to question 17)
h.	Reclast (Zoledronic Acid)	Yes	No (if yes, go to question 17)

Questions 10-15 is for participants taking oral bisphosphonates - all others, skip to question 17.

13. Can you please describe to me how you take your _____? (interviewer – please fill in 11 through 15 based on the participant's responses)

NOTE: If in the participant's response they don't specifically mention one of the following areas (i.e. What they drink with their medication), prompt with each question (11-15) as needed.

- 14. What time of the day do you take your _____?
 - a. First thing in the morning b. Other
- 15. When you take your _____ do you drink anything with it?
 - a. Yes (go to question 13)
 - b. No

16. What do you drink with your _____?

- a. Water
- b. Other (e.g. milk, juice, coffee)

17. When you take your ____ ___, when is the last time you've eaten any food before you take it?

- a. The night before (e.g. before bed)
- b. Other (e.g. right before I take the pill, after breakfast)
- 18. How long after you take your ____ _____do you eat or drink something other than water?
 - a. Less than 30 minutes after taking the medication
 - b. At least 30 minutes (minium wait time for Fosamax and Actonel)
 - c. At least one hour (minimum wait time for Boniva)
- 19. What was your experience in following these special instructions? I will read some responses and let me know which one fits your situation.

No problems	Minor difficulties, but able to take	Lots of difficulties, but able to tal	Stopped taking medications
at all	medication	medication	because of difficulties
1	2	3	4

You indicated that you are taking medication for your osteoporosis. Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your (current medication) (i.e. other than Calcium and Vitamin D).

Please answer each question below by checking the box that best describes your response.

20. Do you sometimes forget to take your?	∱ Yes	μNο
21. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past four weeks, were there any times when you did not take?	∱ Yes	ţNo
22. Have you ever cut back or stopped taking your without telling your doctor, because you felt worse when you took it?	†,¥es	[†] ∎No
23. When you travel or leave home, do you sometimes forget to bring along your?	∱,Yes	[†] ∎No
24. Did you take your the last time you were supposed to take it?	[†] ,Yes	[‡] No
25. If you feel that your is not working, do you sometimes stop taking your medication?	• Yes	[‡] No
26. Taking medication exactly as prescribed is a real inconvenience for some people. Do you ever feel hassled about sticking to your osteoporosis treatment plan?	∱ Yes	[‡] No
27. How often do you have difficulty remembering to take all your medications?		
LNever/Rarely		
∮Once in a while		
\$Sometimes		
‡Usually		
All the time		

- 28. On average how many days a week do you take Calcium pills or antacids that contain calcium (for example: Oscal, Tums, or Caltrate)? Range (0-7) ______ days
- 29. On average how many days a week do you take a daily multivitamin tablet such as Centrum silver, or a store brand such as Wal-Mart, CVS, or Walgreen's? Range (0-7) ______ days
- 30. On average how many days a week do you take Vitamin D, either by itself or as part of a Calcium pill? Range (0-7) _____ days

"Dietary Calcium Lifestyle" questions

31. Do you drink a cup or more of milk or soymilk most days of the week (at least 5 days a week)?

_____ yes: cups per day _____ ____ no

32. Do you eat a cup or more of yogurt most days of the week (at least 5 days a week)?

_____ yes: cups per day _____ ____ no

33. Do you drink a cup or more of orange juice that says "calcium added" on the front most days of the week (at least 5 days a week)?

____yes: _____ cups per day ____no

34. Do you drink dietary supplements like Ensure or Boost most days a week (at least 5 days a week)?

_____ yes: _____ servings per day ______ no

35. Do you eat a slice (ounce) or more of cheese or soy cheese on most days of the week (at least 5 days a week)? (if the participant eats cheese from a block, an ounce is about the size of 4 dice)

Osteoporosis Health Belief Scales

Developed by Katherine K. Kim, Mary Horan, Phyllis Gendler, and Minu Patel Revised for telephone administration (Cadarette, Beaton, & Hawke, 2004) Revised for benefits/barriers for calcium, vitamn D supplements and osteoporosis medicines

Items 28-31 measure osteoporosis susceptibility (subscale)

Items 32-37 measure osteoporosis seriousness (severity) (subscale)

Items 38-40 measure fracture severity (subscale)

Items 41-46 measure benefits to calcium intake (will be tested as a subscale)

Items 47-52 measure benefits to vitamin D intake (will be tested as a subscale)

Items 53-58 measure barriers to calcium supplements (will be tested as a subscale)

Items 59-63 measure barriers to vitamin D supplements (will be tested as a subscale)

Items 64-68 measure perceived benefits of osteoporosis medicines (subscale)

Items 69-70 measure perceived barriers to osteoporosis medicines (subscale)

Items 71-76 measure health motivation (subscale)

Osteoporosis Health Belief Scale (Interviewer: Read the following instructions slowly)

Osteoporosis is a condition in which the bones become excessively thin and weak so that they are fracture prone (break more easily).

I am going to ask you some questions about your beliefs about osteoporosis. There are no right or wrong answers. Everyone has different experiences that will influence how they feel. After I read each statement, tell me if you STRONGLY DISAGREE, DISAGREE, are NEUTRAL, AGREE, or STRONGLY AGREE with the statement. When I read each statement, tell me which of the five is your choice.

It is important that you answer according to your actual beliefs and not according to how you feel you should believe or how you think we want you to believe. We need the answers that best explain how you feel.

think we want you to believe. We need the answers that be	Strongly	you reen			Strongly
	• •	Disagree	Neutral		Agree
	1	2	3	4	5
Susceptibility subscale					
36. Your chances of getting osteoporosis					
are high.	SD	D	Ν	А	SA
37. Because of your body build, you are more likely to develop osteoporosis.	SD	D	Ν	A	SA
 It is extremely likely that you will get osteoporosis. 	SD	D	Ν	A	SA
39. You are more likely than the average person to get osteoporosis.	SD	D	Ν	A	SA
Seriousness subscale					
40. The thought of having osteoporosis scares you.	SD	D	N	А	SA
40. The thought of having osteoporosis scares you.	30	U	IN	A	34
41. If you had osteoporosis you would be crippled.	SD	D	Ν	А	SA
 Your feelings about yourself would change if you got osteoporosis. 	SD	D	Ν	A	SA
43. It would be very costly if you got osteoporosis.	SD	D	Ν	А	SA
44. When you think about osteoporosis you get depressed.	SD	D	N	A	SA
45. It would be very serious if you got osteoporosis.	SD	D	Ν	А	SA
Seriousness subscale (OSTEOPOROSIS) 46. The thought of having osteoporosis scares you.	SD	D	N	A	SA
47. If you have osteoporosis you could be crippled.	SD	D	Ν	А	SA

48. Your feelings about yourself changed because you have osteoporosis.	SD	D	Ν	А	SA
49. It is very costly if you have osteoporosis.	SD	D	Ν	А	SA
50. When you think about osteoporosis you get depressed.	SD	D	Ν	А	SA
51. It is very serious to have osteoporosis.	SD	D	Ν	А	SA
Fracture Severity Subscale 52. Breaking my hip or a bone in my spine would lower my sense of well-being.	SD	D	Ν	A	SA
53. Breaking my hip or a bone in my spine would lower my health permanently.	SD	D	Ν	А	SA
54. Breaking my hip or a bone in my spine could permanently limit my ability to do activities that are important to me	SD	D	Ν	A	SA
Calcium Supplements Perceived Benefits Subscale 55. Taking calcium supplements prevents problems from osteoporosis.	SD	D	Ν	A	SA
 You have lots to gain from taking calcium supplements to prevent osteoporosis. 	SD	D	Ν	А	SA
57. You would not worry as much about osteoporosis if you took calcium supplements.	SD	D	Ν	A	SA
58. Taking calcium supplements does NOT cut down the chances of breaking a bone.	SD	D	Ν	А	SA
59. You feel good enough about yourself when you take calcium supplements to prevent osteoporosis.	SD	D	Ν	A	SA
60. Taking calcium supplements does NOT cut down the chances of getting osteoporosis.	SD	D	Ν	А	SA
Vitamin D Supplement Perceived Benefits Subscale 61. Taking vitamin D supplements prevents problems from osteoporosis.	SD	D	Ν	A	SA
62. You have lots to gain from taking vitamin D supplements to prevent osteoporosis.	SD	D	Ν	А	SA

63. You would not worry as much about osteoporosis if you took vitamin D supplements.	SD	D	Ν	A	SA
64. Taking vitamin D supplements does NOT cut down the chances of breaking a bone.	SD	D	Ν	A	SA
65. You feel good enough about yourself when you take vitamin D supplements to prevent osteoporosis.	SD	D	Ν	А	SA
66. Taking vitamin D supplements does NOT cut down the chances of getting osteoporosis.	SD	D	Ν	A	SA
Calcium Supplements Perceived Barriers Subscale 67. You believe you get all the calcium you need from what you eat and drink	SD	D	Ν	А	SA
68. Calcium supplements are hard for you to swallow.	SD	D	Ν	А	SA
69. Calcium supplements do NOT cost too much.	SD	D	Ν	А	SA
70. You do not mind taking calcium supplements.	SD	D	Ν	А	SA
71. Calcium supplements do not agree with you.	SD	D	Ν	А	SA
72. Taking calcium supplements requires changing your routine, which is hard to do.	SD	D	Ν	А	SA
73. You do not like taking calcium supplements because you already take too many pills.	SD	D	Ν	А	SA
Vitamin D Supplements Perceived Barriers Subscale 74. You believe you get all the vitamin D you need from what you eat and drink	SD	D	N	A	SA
75. Vitamin D supplements are hard for you to swallow.	SD	D	Ν	A	SA
76. Vitamin D supplements do NOT cost too much.	SD	D	Ν	А	SA
77. You believe you get all of the vitamin D you need from the sun.	SD	D	Ν	А	SA
78. You do not mind taking vitamin D supplements.	SD	D	Ν	А	SA
79. You do not like taking vitamin D supplements because you already take too many pills.	SD	D	Ν	A	SA

Perceived Benefits of Prescription Antiresorptives Subscale 80. Drug treatments can help build strong bones	SD	D	Ν	A	SA
81. You would feel good about taking drug treatments to prevent osteoporosis	SD	D	Ν	A	SA
82. Drug treatments can cut down the chances of broken bones	SD	D	Ν	A	SA
83. You would consider taking drug treatments to prevent broken bones	SD	D	Ν	A	SA
84. If your doctor advised you to, you would take drug treatments to prevent broken bones	SD	D	Ν	A	SA
Perceived Barriers to the Use of Prescription Antiresorptives 85. Prescription medicines for osteoporosis are more trouble than they are worth	Subscale SD	D	Ν	A	SA
86. Prescription medicines for osteoporosis can cause a lot of side effects	SD	D	Ν	A	SA
Health Motivation Subscale					
87. You eat a well-balanced diet.	SD	D	Ν	А	SA
88. You look for new information related to your health.	SD	D	Ν	A	SA
89. Keeping healthy is very important for you.	SD	D	Ν	А	SA
90. You try to discover health problems early.	SD	D	Ν	A	SA
91. You have a regular health check-up even when you are not sick.	SD	D	Ν	A	SA
92. You follow recommendations to keep healthy.	SD	D	Ν	А	SA

		Agree				
	Completely	mostly	somewhat	Somewhat	mostly	completely
I am convinced of the importance of						
my prescription medication.	1	2	3	4	5	6
I worry that my prescription medication						
will do more harm than good to me	1	2	3	4	5	6
I fell financially burdened by my out-of-pocket expenses for my						
prescription medication	1	2	3	4	5	6

Osteoporosis & You Knowledge Scale

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
93.	Age-related height loss is a symptom of osteoporosis	1	2	3	4	5
94.	The risk of having osteoporosis is higher after menopause	1	2	3	4	5
95.	l have a greater chance of having osteoporosis if my mother or father has/had it	1	2	3	4	5
96.	Eating foods high in calcium and vitamin D can help slow the rate of bone loss	1	2	3	4	5
97.	Exercising every day can help slow the rate of bone loss	1	2	3	4	5
98.	There is no way to prevent osteoporosis	1	2	3	4	5
99.	A woman/man may have osteoporosis for years but not know this until she/he breaks a bone	1	2	3	4	5
100.	If a woman/man has osteoporosis, something as simple as lifting a bag of groceries can break a bone	1	2	3	4	5
101.	Bones cannot be rebuilt once they thin from osteoporosis	1	2	3	4	5
102.	The health problems caused by osteoporosis can be life-threatening	1	2	3	4	5

Now I am going to ask you some questions about osteoporosis. After I read each statement, tell me if you strongly disagree, disagree, neither disagree nor disagree, agree or strongly agree with each statement.

Self-Efficacy Scale for Osteoporosis Medication Adherence (includes calcium and vitamin D supplements) Interviewer: I am going to ask you how confident you feel that you will take your medicine for osteoporosis in several different situations. Many everyday situations can make it difficult to take prescribed medications as you intend to take them. Medicines for osteoporosis include calcium and vitamin D, hormone replacement therapy such as estrogen (Premarin, Prempro, Estrace), Miacalcin nose spray, or bone builders such as Fosamax, Actonel, Boniva, or Forteo. On a scale of 0 to 10, where 0 is no confidence and 10 is total confidence, how confident are you that you will take your ______ (if applicable) under each of the following conditions?

		Not at all confident	Not very confident	Somewhat confident	Very confident	Totally confident
103.	You are feeling well? (NOT IN ORIGINAL LIST)	1	2	3	4	5
104.	You are feeling ill?	1	2	3	4	5
105.	You are away from home?	1	2	3	4	5
106.	You are sad and blue?	1	2	3	4	5
107.	You have a busy day scheduled?	1	2	3	4	5
108.	No one reminds you to take the medicine?	1	2	3	4	5
109.	The schedule to take the medicine is inconvenient?	1	2	3	4	5
110.	You are having pain.	1	2	3	4	5
111.	You are feeling strong and healthy.	1	2	3	4	5
112.	You are feeling sick to your stomach.	1	2	3	4	5
113.	The drug is expensive.	1	2	3	4	5
114.	The pills are hard to swallow.	1	2	3	4	5
115.	Your normal routine is interrupted.	1	2	3	4	5
116.	Your are not certain how or when to take the medication.	1	2	3	4	5
117.	The medication upsets your stomach, causes constipation, or other side effects.	1	2	3	4	5

118. How high do you think your chances are of breaking a bone in the next 10 years?f. About 1 in a hundred people like me will have a broken bone.

- g. About 5 in a hundred people like me will have a broken bone.
- h. About 10 in a hundred people like me will have a broken bone.
- i. About 20 in a hundred people like me will have a broken bone.
- j. About 35 in a hundred people like me will have a broken bone.

119. (ONLY FOR PATIENTS NOT CURRENTLY ON A MEDICATION)

Please choose the statement that best reflects your thoughts on treatment options for osteoporosis.

1. I have never heard of osteoporosis. I am unaware of any treatment for osteoporosis.

2. I am aware that there are treatments available for osteoporosis, but I have never thought seriously about using these medications.

- 3. I have considered using medications to treat osteoporosis, but I have decided against it. (This includes anyone who has taken medication in the past for prevention or treatment but is no longer using any medication)
- 4. I am currently considering the use of medications to treat osteoporosis, but I have not made up my mind.
- 5. I have decided to use medication to treat osteoporosis but I have not yet started taking anything.
- 120. (ONLY FOR PATIENTS CURRENTLY ON A MEDICATION)

How likely are you to stop taking (current medication)? On a scale from 0-10, where 0 is not at all likely and 10 is very likely?

Not at a	all likely to	o stop								Very likely to stop
0	1	2	3	4	5	6	7	8	9	10
Thank you very much for your time. That concludes our survey.										

Would it be okay to call you again in about 4 months to follow-up with a few more questions and to see how you are doing?

Is there any update to your contact information?

(For everyone) Full name Street Address City, State

In case you move and we have trouble reaching you in four months, please also provide me information for contact people that will know how to reach you.

Contact 1: Name Street Address City, State Telephone Number Relation

Contact 2: Name Street Address City, State Telephone Number Relation

Thank you again for your help and your time.

APPENDIX C

Subscale Testing Survey

Name	:	
Date:		

Circle One: Test Retest

Calcium, Vitamin D, Sunlight Exposure Subscale Reliability Testing Telephone script and survey

Hello! My name is . I'm calling on behalf of the University of Alabama at Birmingham.

Recently, you had a bone density test at the Kirklin Clinic. At that time you told us that you were interested in helping us out with osteoporosis research. I am hoping that you will help us out today. I am conducting a survey on calcium and vitamin D and would like to ask you some questions. The title of this survey is: Testing Health Belief Subscales for Calcium and Vitamin D Supplements in a High Risk for Osteoporosis population (IRB protocol #X090814007). This survey is being used for research purposes only. Is this a good time to talk?

I need to ask you one question that may keep you from qualifying from taking this survey. Are you now taking or have you taken in the past, a high dose vitamin D supplement that your doctor prescribed for you?

If yes: thank you so much but for the purposes of this survey, we can't use people who have taken high dose vitamin D.

If no: thank you (proceed to next section):

This call will take about 20 minutes. I will also be calling you again to interview you again in two weeks. At the completion of the second telephone survey, we will mail you a \$20 VISA gift card.

Before we continue, there are a couple of things that I need to tell you. The purpose of this study is to develop a survey that tells us about how people feel about taking dietary supplements and about people's outdoor habits.

All information you provide is confidential. You will not be identified by name and no information will be shared with anyone.

Your participation in this interview is voluntary. There will be no penalty if you decide not to be in the study. You are free to withdraw from this study at any time. Your choice to not participate or leave this study will not affect your relationship with the University of Alabama at Birmingham in any way. The principal investigator is Beth Kitchin. You can contact her at 934.7474

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB) at the University of Alabama at Birmingham (UAB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Do you have any questions?

- □ Yes (If yes, respond to their questions)
- 🗆 No

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(If patient indicates not interested) Thank you for your time. Have a good day!

(If patient indicates that now is not a good time) When would it be a good time to call back Day , Time

(If interested) Great!

In case we get disconnected and I need to call you back, what is your telephone number?

There are no right or wrong answers to any of the questions I will be asking-just answer the best you can. If I ask you any question you would prefer not to answer, just let me know and I'll move on to the next question.

- 1. How high do you think your chances are of breaking a bone in the next 10 years?
 - a. 1 in 100 b. 1 in 10 c. 1 in 5
 - d. 1 in 2
- On average, how many days a week do you take calcium pills or calcium antacids (for example: Tums, Caltrate, Oscal, or Viactiv or a store brand such as Wal-Mart, CVS, or Walgreen's) Range (0-7) _____ days
- On average, how many days a week do you take a multivitamin tablet such as Centrum Silver, One-A-Day, or a store brand such as Wal-Mart, CVS, or Walgreen's? Range (0-7) _____ days
- 4. On average, how many days a week do you take Vitamin D, either by itself or as part of a calcium pill?

Range (0-7) _____ days

Now, I am going to read you a series of statements and then ask you if you strongly disagree, disagree, feel neutral, agree, or strongly agree with the statement.

Calcium Supplements Perceived Benefits5. Taking calcium supplements prevents problems from osteoporosis.	SD	D	Ν	А	SA
 You have lots to gain from taking calcium supplements to prevent osteoporosis. 	SD	D	Ν	А	SA
 You would not worry as much about osteoporosis if you took calcium supplements. 	SD	D	Ν	А	SA
8. Taking calcium supplements does not cut down	SD	D	Ν	А	SA
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the chances of breaking a bone.

You feel good about yourself when you take calcium supplements to prevent osteoporosis.	SD	D	Ν	А	SA
10. Taking calcium supplements does not cut down the chances of getting osteoporosis.	SD	D	Ν	А	SA
Vitamin D Supplement Perceived Benefits 11. Taking vitamin D supplements prevents problems from osteoporosis.	SD	D	Ν	А	SA
 You have lots to gain from taking vitamin D supplements to prevent osteoporosis. 	SD	D	Ν	А	SA
 You would not worry as much about osteoporosis if you took vitamin D supplements. 	SD	D	Ν	А	SA
14. Taking vitamin D supplements does not cut down the chances of breaking a bone.	SD	D	Ν	А	SA
 You feel good about yourself when you take vitamin D supplements to prevent osteoporosis. 	SD	D	Ν	А	SA
16. Taking vitamin D supplements does not cut down the chances of getting osteoporosis.	SD	D	Ν	А	SA
Calcium Supplements Perceived Barriers 17. You believe you get all the calcium you need from what you eat and drink.	SD	D	Ν	А	SA
18. Calcium supplements are hard for you to swallow.	SD	D	Ν	А	SA
19. Calcium supplements do not cost too much.	SD	D	Ν	А	SA
20. You do not mind taking calcium supplements.	SD	D	Ν	А	SA
21. Calcium supplements do not agree with you.	SD	D	Ν	А	SA
22. Taking calcium supplements requires changing your routine, which is hard to do.	SD	D	Ν	А	SA
 You do not like taking calcium supplements because you already take too many pills. 	SD	IJ	Ν	А	SA
Vitamin D Supplements Perceived Barriers24. You believe you get all the vitamin D you need from what you eat and drink.	SD	D	Ν	А	SA
25. Vitamin D supplements are hard for you to swallow.	SD	D	Ν	А	SA
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26. Vitamin D supplements do not cost too much.	SD	D	Ν	А	SA
27. You believe you get all of the vitamin D you need from the sun.	SD	D	Ν	А	SA
28. You do not mind taking vitamin D supplements.	SD	D	Ν	А	SA
 You do not like taking vitamin D supplements because you already take too many pills. 	SD	D	Ν	А	SA

Thank you for helping me out with those questions. You did a great job! Now I would like to ask you a few questions about what you eat and drink. Remember, there are no right or wrong answers. I just want you to answer the best you can.

"Dietary Calcium Lifestyle" questions

30. Do you drink a cup or more of milk or soymilk most days of the week (at least 5 days a week)?

_____ yes: cups per day _____ _____ no

31. Do you eat a cup or more of yogurt most days of the week (at least 5 days a week)?

_____yes: cups per day ______

32. Do you drink a cup or more of orange juice that says "calcium added" on the front most days of the week (at least 5 days a week)?

____yes: _____ cups per day no

33. Do you drink dietary supplements like Ensure or Boost most days a week (at least 5 days a week)?

_____ yes: _____ servings per day

34. Do you eat a slice (ounce) or more of cheese or soy cheese on most days of the week (at least 5 days a week)? (if the participant eats cheese from a block, an ounce is about the size of 4 dice)
 yes: _________ slice per day ________

After that second call, I will be sending you a \$20 Visa gift card. Is your mailing address still:

Address:

Thank you so much for your time and help today. I look forward to talking with you again!

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